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PART IX

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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CLASSIFICATION OF MEDICAL DEVICES

Development of General Provisions; Proposed Rules

[4110-03-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR PART 870]

[Docket No. 78N-1406]

CLASSIFICATION OF CARDIOVASCULAR DEVICES

Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Agency is proposing general rules applicable to the classification of all cardiovascular devices. The Medical Device Amendments of 1976 require the Food and Drug Administration (FDA) to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual cardiovascular devices, which are being published elsewhere in this issue of the FEDERAL REGISTER. The preamble also describes the activities of the Cardiovascular Device Classification Panel, an FDA advisory committee, that makes recommendations to FDA concerning the classification of cardiovascular devices.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

DEVICE CLASSIFICATION SYSTEM

The Medical Device Amendments of 1976 (Pub. L. 94-295, hereinafter called the amendments) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows:

Class I, general controls;

Class II, performance standards; and

Class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the Panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

RELATED REGULATIONS

In the FEDERAL REGISTER of July 28, 1978 (43 FR 32988), The Commissioner issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the FEDERAL REGISTER of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the FEDERAL REGISTER of May 19, 1975 (40 FR 21848).

ACTIVITIES OF PANEL

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Cardiovascular Device Classification Panel (the Panel) was originally chartered on October 15, 1974, as the Panel on Review of Cardiovascular Devices. The FDA placed a report of the Panel's tentative classification recommendations on file with the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the FEDERAL REGISTER of September 9, 1975 (40 FR 41829). On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments.

Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of cardiovascular devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In October 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and former Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the FEDERAL REGISTER of November 29, 1977 (42 FR 60792). At subsequent meetings, the Panel changed its previous recommendations concerning the classification of several devices. Summary minutes of these meetings have been placed in the office of the Hearing Clerk, Food and Drug Administration. Also available in the office of the Hearing Clerk are summary minutes form all other Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual cardiovascular device proposed classification regulations. Interested persons may review these documents in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between 9 a.m. and 4 p.m., Monday through Friday.

LIST OF CARDIOVASCULAR DEVICES

In 1972 FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of cardiovascular devices. The Panel supplemented the list utilizing its members' knowledge of

cardiovascular devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not usually included. Although the Panel recommended that artificial hearts be classified into class III, none were commercially available at the time the law was enacted, and therefore artificial hearts have not been included in the list of cardiovascular devices, and no regulation is being proposed for them. The Panel recommended that pacemaker batteries be classified as a distinct device into class II. However, FDA believes that, because they are components of pacemaker pulse generators, the batteries should be regulated as a part of the pulse generators. Therefore, pacemaker batteries have been deleted from the list, and no regulation is proposed for them. Additional cardiovascular devices, which are not included in this list and which were commercially available before May 28, 1976, will be added to the list as necessary.

FDA is proposing to establish a new Part 870 in Title 21 of the Code of Federal Regulations. Part 870 will consist of sections identifying each cardiovascular device with a brief narrative description and stating the classification of that device. A list of the cardiovascular devices appears elsewhere in this preamble.

Individual Cardiovascular Device Classification Regulations

Elsewhere in this issue of the Federal Register, FDA is issuing 142 individual proposed regulations to classify each cardiovascular device. FDA is proposing to classify 2 cardiovascular devices into class I (general controls), 114 cardiovascular devices into class II (performance standards) and 26 cardiovascular devices into class III (premarket approval). The Commissioner also is publishing the recommendations of the Panel regarding these devices, as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Published Panel Recommendations

Each published Panel recommendation concerning a cardiovascular device includes the information described below.

1. *Indentification.* Both the Panel recommendation and the proposed FDA classification regulation include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 870.1, any manufacturer of a newly offered device who files premarket notification submission under section 510(k) of the act and Part 807 of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendment device (or to a postamendment device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The Commissioner believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). The Panel did not recommend any exemptions for devices for which the Panel recommended classification into class I. Manufacturers and other interested persons may submit comments on the appropriateness of exempting manufacturers of particular class I devices from one or more of the requirements under sections 510, 519, and 520(f) of the act. These comments should be supported by data and views showing that the application of these requirements to manufacturers of a device is not necessary to assure that the device is safe and effective and in compliance with the act, and that, despite the exemption, FDA will be able to discharge its regulatory responsibilities under the act.

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high," "medium," or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "priorities for Class II and III Devices," the Commissioner is not, however, proposing the establishment of agency priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, the Commissioner is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The summary of reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporting or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on the Panel members' personal knowledge of, and familiarity with, the devices under review. The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(a)(2) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rep. No. 94-853, 94th Congress, 2d Session 40 (1976)). The Commissioner has de-

termined that clinical experience and judgment constitute valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual cardiovascular device regulations. The Commissioner is adopting as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by cardiovascular devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the individual device. Among the more frequently identified risks, the Panel listed thromboembolism, gaseous or particulate embolism, cardiac arrhythmias or electrical shock, cardiac perforation and vessel dissection, tissue or blood damage, and misdiagnosis. All cardiovascular devices that have a direct interface with the blood have the potential of causing embolisms, obstructions or occlusions of a blood vessel by an air bubble (gas embolism), detached blood clot (thromboembolism) or other foreign body (particulate embolism). Many electrically operated devices can cause cardiac arrhythmias (disturbances of the normal rhythm of the heart) or electrical shock to the physician, leading to iatrogenic (physician induced) complications in the patient. The Panel stated that most devices used in cardiac catheterization can cause perforation of the heart muscle or can dissect the vessels in which the device is inserted. Tissue and blood damage caused by a cardiovascular device may result from mechanical trauma, emission of excessive energy by the device, incompatibility of materials with the blood or tissue, or electrical and thermal burns. The Panel recognizes that infection is a hazard posed by any device which is required to be sterile, especially implanted devices. Yet, in many cases, the Panel did not list infection as a risk because it believes that assurance of sterility is addressed by general controls. Finally, the Panel recognizes that any device used to diagnose a patient's condition can generate inaccurate diagnostic data, which may lead to a misdiagnosis and inappropriate therapy and, hence, may pose a significant risk to the patient's health. Accordingly, this risk is noted in each of the documents for diagnostic devices.

Because the classification recommendations and FDA regulations may not identify all risks to health presented by cardiovascular devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each proposed regulation to classify a cardiovascular device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 870 in which the device classification will be codified.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends classification into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of performance standards or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II or class III, the Panel compared the device with other cardiovascular devices, based on information availabale to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panel recommended assignment of a "high priority" only to those class II or class III devices that the Panel believed should receive the agency's immediate attention.

The Commissioner is not proposing at this time to establish priorities for development of performance standards for class II devices or application of premarket approval requirements to class III devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. At a later date, however, the Commissioner will establish priorities for the development of standards for class II devices and the application of premarket approval requirements to class III devices. These priorities will be based on the classification panel's recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the Federal Register.

The agency intends to proceed as quickly as the statute and classification panel resources permit to require premarket approval of devices classified into class III. There are two factors affecting the length of time necessary before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a classification panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the Panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification during which a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

List of Cardiovascular Devices

The following is a list of the cardiovascular devices that FDA is proposing to classify, the section in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Subpart B—Cardiovascular Diagnostic Devices

Section	Device	Docket No.	Class
870.1025	Arrhythmia detector and alarm	78N-1407	III
870.1100	Blood pressure alarm	78N-1408	II
870.1110	Blood pressure computer	78N-1409	II
870.1120	Blood pressure cuff	78N-1410	II
870.1130	Noninvasive blood pressure measurement system	78N-1411	II
870.1140	Venous blood pressure manometer	78N-1412	II
870.1200	Diagnostic intravascular catheter	78N-1413	II
870.1210	Continuous flush catheter	78N-1414	II
870.1220	Electrode recording catheter and electrode recording probe	78N-1415	II
870.1230	Fiberoptic oximeter catheter	78N-1416	II
870.1240	Flow-directed catheter	78N-1417	II
870.1250	Percutaneous catheter	78N-1418	II
870.1260	pH catheter probe	78N-1419	II
870.1270	Intracavitary phono catheter system	78N-1420	II
870.1280	Steerable catheter	78N-1421	II
870.1290	Steerable catheter control system	78N-1422	II
870.1300	Catheter cannula	78N-1423	II
870.1310	Vessel dilator for percutaneous catheterization	78N-1424	II
870.1320	Catheter guide holder	78N-1425	I
870.1330	Catheter guide wire	78N-1426	II
870.1340	Catheter percutaneous introducer	78N-1427	II
870.1350	Catheter ballon repair kit	78N-1428	III
870.1360	Trace microsphere	78N-1429	III
870.1370	Catheter tip occluder	78N-1430	II
870.1380	Catheter stylet	78N-1431	II
870.1390	Trocar	78N-1432	II
870.1425	Programmable diagnostic computer	78N-1433	II
870.1435	Single-function, preprogrammed diagnostic computer	78N-1434	II
870.1450	Densitometer	78N-1435	II
870.1650	Angiographic injector and syringe	78N-1436	II
870.1660	Indicator injector	78N-1437	II
870.1670	Syringe actuator for injectors	78N-1438	II
870.1750	External programmable pacemaker pulse generator	78N-1439	II
870.1800	Withdrawal-infusion pump	78N-1440	II
870.1875	Stethoscope	78N-1441	II
870.1915	Thermodilution probe	78N-1442	II

Subpart C—Cardiovascular Monitoring Devices

870.2050	Biopotential amplifier and signal conditioner	78N-1443	II
870.2060	Transducer signal amplifier and signal conditioner	78N-1444	II
870.2100	Cardiovascular blood flowmeter	78N-1445	II
870.2120	Extravascular blood flow probe	78N-1446	II
870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	78N-1447	II
870.2310	Apex cardiograph (vibrocardiograph)	78N-1448	II
870.2320	Ballistocardiograph	78N-1449	II
870.2330	Echocardiograph	78N-1450	II
870.2340	Electrocardiograph	78N-1451	II
870.2350	Electrocardiograph lead switching adaptor	78N-1452	II
870.2360	Electrocardiograph electrode	78N-1453	II
870.2370	Electrocardiograph surface electrode tester	78N-1454	II
870.2380	Electrocardiograph conducting media	78N-1455	II
870.2390	Phonocardiograph	78N-1456	II
870.2400	Vectorcardiograph	78N-1457	II
870.2450	Medical cathode-ray tube display	78N-1458	II
870.2600	Signal isolation system	78N-1459	II
870.2620	Line isolation monitor	78N-1460	II
870.2640	Portable leakage current alarm	78N-1461	II
870.2675	Oscillometer	78N-1462	II
870.2700	Oximeter	78N-1463	II
870.2710	Ear oximeter	78N-1464	II
870.2750	Impedance phlebograph	78N-1465	II
870.2770	Impedance plethysmograph	78N-1466	II
870.2780	Hydraulic, pneumatic, and photoelectric plethysmograph	78N-1467	II
870.2800	Medical magnetic tape, recorder	78N-1468	II
870.2810	Paper chart recorder	78N-1469	II
870.2840	Apex cardiographic transducer	78N-1470	II
870.2850	Extravascular blood pressure transducer	78N-1471	II
870.2860	Heart sound transducer	78N-1472	II
870.2870	Catheter tip pressure transducer	78N-1473	II
870.2880	Ultrasonic transducer	78N-1474	II
870.2890	Vessel occlusion transducer	78N-1475	II
870.2900	Patient transducer and electrode cable (including connector)	78N-1476	II
870.2910	Radiofrequency physiological signal transmitters and receivers	78N-1477	II
870.2920	Telephone electrocardiograph transmitters and receivers	78N-1478	II

Subpart D—Cardiovascular Prosthetic Devices

870.3250	Vascular clip	78N-1479	II
870.3260	Vena cava clip	78N-1480	II
870.3300	Peripheral arterial embolization device	78N-1481	III
870.3375	Cardiovascular intravascular filter	78N-1482	III
870.3450	Vascular graft prosthesis of less than 6mm diameter	78N-1483	III
870.3460	Vascular graft prosthesis of 6mm and greater diameter	78N-1484	II
870.3470	Intracardiac patch and pledget made of polypropylene, Teflon, or Dacron	78N-1485	II
870.3535	Intra-aortic balloon and control system	78N-1487	III
870.3545	Ventricular bypass (assist) devices	78N-1488	III
870.3600	External pacemaker pulse generator	78N-1489	III
870.3610	Implantable pacemaker pulse generator	78N-1490	III
870.3620	Pacemaker lead adaptor	78N-1491	III
870.3630	Pacemaker generator function analyzer	78N-1492	II
870.3640	Indirect pacemaker generator function analyzer	78N-1493	II
870.3650	Pacemaker polymeric mesh bag	78N-1494	II
870.3670	Pacemaker charger	78N-1496	II
870.3680	Permanent and temporary pacemaker electrode	78N-1497	III
870.3690	Pacemaker test magnet	78N-1498	II
870.3700	Pacemaker programmer	78N-1499	III
870.3710	Pacemaker repair and replacement materials	78N-1500	III
870.3720	Pacemaker electrode function tester	78N-1501	II
870.3730	Pacemaker service tools	78N-1502	I
870.3800	Annuloplasty ring	78N-1503	III
870.3850	Carotid sinus nerve stimulator	78N-1504	III
870.3925	Replacement heart valve	78N-1505	III
870.3935	Prosthetic heart valve holder	78N-1506	II
870.3945	Prosthetic heart valve sizer	78N-1507	II
870.4075	Endomyocardial biopsy device	78N-1508	II
870.4200	Cardiopulmonary bypass accessory equipment	78N-1509	II
870.4205	Cardiopulmonary bypass bubble detector	78N-1378	II
870.4210	Cardiopulmonary bypass vascular catheter, cannula, and tubing	78N-1510	II
870.4220	Cardiopulmonary bypass heart-lung machine console	78N-1511	II
870.4230	Cardiopulmonary bypass defoamer	78N-1512	III
870.4240	Cardiopulmonary bypass heat exchanger	78N-1513	II
870.4250	Cardiopulmonary bypass temperature controller	78N-1514	II
870.4260	Cardiopulmonary bypass arterial line blood filter	78N-1515	III
870.4270	Cardiopulmonary bypass cardiotomy suction line blood filter	78N-1516	II
870.4280	Cardiopulmonary pre-bypass filter	78N-1517	II
870.4290	Cardiopulmonary bypass fitting, manifold, stopcock and adaptor	78N-1518	II
870.4300	Cardiopulmonary bypass gas control unit	78N-1519	II
870.4310	Cardiopulmonary bypass coronary pressure gauge	78N-1520	II
870.4320	Cardiopulmonary bypass pulsatile flow generator	78N-1521	III
870.4330	Cardiopulmonary bypass on-line blood gas monitor	78N-1522	II
870.4340	Cardiopulmonary bypass level sensing monior and/or control	78N-1523	II
870.4350	Cardiopulmonary bypass oxygenator	78N-1524	III
870.4360	Nonroller type cardiopulmonary bypass blood pump	78N-1525	III
870.4370	Roller-type cardiopulmonary bypass blood pump	78N-1526	II
870.4380	Cardiopulmonary bypass pump speed control	78N-1527	II
870.4390	Cardiopulmonary bypass pump tubing	78N-1528	II
870.4400	Cardiopulmonary bypass blood reservoir	78N-1529	II
870.4410	Cardiopulmonary bypass in-line blood gas sensor	78N-1530	II
870.4420	Cardiopulmonary bypass cardiotomy return sucker	78N-1531	II
870.4430	Cardiopulmonary bypass intracardiac suction control	78N-1532	II
870.4450	Vascular clamp	78N-1533	II
870.4475	Surgical vessel dilator	78N-1534	II
870.4500	Cardiovascular surgical instruments	78N-1535	II
870.4875	Intraluminal artery stripper	78N-1536	II
870.4885	External vein stripper	78N-1537	II
870.5050	Patient care suction apparatus	78N-1538	II
870.5150	Embolectomy catheter	78N-1539	II
870.5175	Septostomy catheter	78N-1540	II
870.5200	External cardiac compressor	78N-1541	III
870.5225	External counterpulsating device	78N-1542	III
870.5300	DC-defibrillator (including paddles)	78N-1543	III
870.5325	Defibrillator tester	78N-1544	II
870.5550	External transcutaneous cardiac pacemaker (noninvasive)	78N-1545	III
870.5800	Compressible limb sleeve	78N-1546	II
870.5900	Thermal regulating system	78N-1547	II
870.5925	Automatic rotating tourniquet	78N-1548	II

DEVICES CONSIDERED BY TWO OR MORE PANELS

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendation and a single proposed classification regulation. The following devices were considered by the Cardiovascular Device Classification Panel and by other panels:

1. The Neurological Device Classification Panel recommended that angiographic needles be classified into class I. The Cardiovascular Device Classification Panel recommended that catheter trocars be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying catheter trocars. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class II and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

2. The Neurological Device Classification Panel recommended that angiographic guide wires and accessories be classifed into class I. The Radiological Device Classification Panel recommended that radiological catheter guide wire be classified into class II. The Cardiovascular Device Classification Panel recommended that cardiovascular guide wires be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying catheter guide wires. Bases upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class II and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

3. The General and Plastic Surgery Device Classification Panel recommended that nonpowered central venous pressure monitors and nonpowered peripheral venous pressure monitors be classified into class I. The Cardiovascular Device Classification Panel recommended that venous blood pressure manometers be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying venous blood pressure manometers. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class II and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

4. The General and Plastic Surgery Device Classification Panel recommended that direct stethoscopes and electronic amplified stethoscopes be classified into class I. The General Hospital and Personal Use Device Classification Panel recommended that mechanical stethoscopes and DC-powered stethoscopes be classified into class I. The Cardiovascular Device Classification Panel recommended that stethoscopes be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying stethoscopes. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class II and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

5. The Anesthesiology Device Classification Panel recommended that mechanical cardiac resuscitators be classified into class III. The General Hospital and Personal Use Device Classification Panel recommended that manual external cardiac compressors be classified into class III and that powered external cardiac compressors be classified into class II. The Cardiovascular Device Classification Panel recommended that external cardiac compressors be classified into class III. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying external cardiac compressors. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class III and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

6. The General and Plastic Surgery Device Classification Panel recommended that synthetic arterial graft prostheses (less than 6mm diameter) be classified into class III. The Cardiovascular Device Classification Panel recommended that vascular graft prostheses (less than 6mm diameter) be classified into class III. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying vascular graft prostheses (less than 6mm diameter) into class III and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

7. The Cardiovascular Device Classification Panel and the other Panels listed below recommended classification into class II for the following devices:

Device	Other panel(s)
Flow directed catheter	
Ballon-type cardiovascular catheter	General and Plastic Surgery
Diagnostic intravascular catheter	
Angiographic catheter	Neurological
Cardiovascular catheter	General and Plastic Surgery
Opaque vascular catheter	Radiology
Blood pressure computers	
Internal arterial pressure monitor	General and Plastic Surgery
Atrial cardiac pressure monitor	General and Plastic Surgery
Ventricular cardiac pressure monitor	General and Plastic Surgery
Powered pulmonary artery pressure monitor	General and Plastic Surgery
Indwelling blood pressure monitor	Anesthesiology
Invasive neonatal blood pressure monitor	General Hospital and Personal Use
Single-function, preprogrammed diagnostic computer	
Dye cardiac output monitor	General and Plastic Surgery
Thermal cardiac output monitor	General and Plastic Surgery
Trend cardiac output monitor	General and Plastic Surgery
Blood pressure cuff	
Nonpowered external arterial pressure monitor	General and Plastic Surgery
Inflation cuff	General and Plastic Surgery
Manual cuff inflating air pump	General and Plastic Surgery
Noninvasive blood pressure measurement system	
Nonindwelling blood pressure monitor	Anesthesiology
Powered external arterial pressure monitor	General and Plastic Surgery
Aneroid blood pressure manometer	General and Plastic Surgery
Mercury blood pressure manometer	General and Plastic Surgery
Ultrasonic/doppler neonatal blood pressure monitor	General and Plastic Surgery
Electrocardiograph	
Electrocardiograph monitor	General and Plastic Surgery
Electrocardiograph monitor	Anesthesiology
Cardiovascular blood flowmeter	
Transcutaneous ultrasonic blood flowmeter	Anesthesiology
Flowmeter cardiac output monitor	General and Plastic Surgery
Electromagnetic or Doppler, noninvasive blood flowmeter	Urology
Electrovascular blood flow probe	
Indwelling blood flow transducer	Anesthesiology
Nonindwelling blood flow transducer	Anesthesiology
Cardiac monitor (including cardiotachometer and rate alarm)	
Pulse rate monitor	Anesthesiology
Neonatal heart rate monitor	General Hospital and Personal Use
Impedance plethysmograph	
Impedance plethymography cardiac output monitor	General and Plastic Surgery
Extravascular blood pressure transducer	
Nonindwelling blood pressure transducer monitor	Anesthesiology
Catheter tip pressure transducer	
Indwelling blood pressure transducer monitor	Anesthesiology
Transducer signal amplifier and signal conditioner	
Blood pressure monitor amplifier and associated electronics	Anesthesiology
Paper chart recorder	
Ophthalmic analog and digital recorder	Ophthalmic
Vascular graft prosthesis (6mm and greater diameter)	
Synthetic arterial graft prosthesis (6mm and greater diameter)	General and Plastic Surgery

The Commissioner has determined that, by group as listed here, these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying each of the groups of devices listed above into class II, using the Cardiovascular Device Classification Panel designation, and is publishing the Panel recommendations in proposals appearing elsewhere in this issue of the FEDERAL REGISTER.

8. The Cardiovascular Device Classification Panel and the other Panels listed below made classification recommendations concerning the following devices:

Device	Other panel(s)
Electrosurgical electrode gel	General and Plastic Surgery Neurological Anesthesiology Dental
Electrosurgical electrode	General and Plastic Surgery Neurological Anesthesiology Dental Gastroenterology and Urology
Electrosurgical device	General and Plastic Surgery Neurological Anesthesiology Dental Gastroenterology and Urology
Pneumatically powered saw	General and Plastic Surgery Orthopedic Neurological Dental Ear, Nose and Throat
Electrically powered saw	General and Plastic Surgery Orthopedic Neurological

Device	Other panel(s)
Electrically powered saw	Dental Ear, Nose and Throat
Surgical saw blade	General and Plastic Surgery
Medical support stocking	General Hospital and Personal Use Physical Medicine
Biopsy needle	General and Plastic Surgery Gastroenterology and Urology Dental
Infusion pump	General Hospital and Personal Use Gastroenterology and Urology
Long-term vascular catheter	General Hospital and Personal Use General and Plastic Surgery
Sutures	General and Plastic Surgery Dental Ophthalmic

The Commissioner is not at this time publishing the Cardiovascular Device Classification Panel recommendations to classify the devices listed above. The Commissioner will publish these recommendations and proposed classification regulations when he publishes the recommendations of the other Panels that reviewed the devices.

ARTERIAL GRAFT PROSTHESES OF ANIMAL (INCLUDING HUMAN) ORIGIN

At a future date, FDA will publish in the FEDERAL REGISTER a final regulation stating that one cardiovascular device (arterial graft prostheses of animal (including human) origin) is classified into class III (premarket approval) because of transitional provisions of the act, section 520(1) (21 U.S.C. 360j(1)). The transitional provisions classify into class III any device previously regarded by FDA as a new drug. At the time FDA publishes this regulation it will also publish the Panel's recommendations regarding arterial grafts of animal (including human) origin.

ENVIRONMENTAL IMPACT

The Commissioner has carefully considered the environmental effects of proposed § 870.1 and of the proposed cardiovascular device classification regulations. Because the proposed actions will not significantly affect the quality of the human environment, the agency has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the office of the Hearing Clerk, Food and Drug Administration (address above).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))), and under authority delegated to the Commissioner (21 CFR 5.1), the Commissioner proposes that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 870, Subpart A, to read as follows:

PART 870—CARDIOVASCULAR DEVICES

Subpart A—General Provisions

Sec.
870.1 *Scope.*

AUTHORITY: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 870.1 Scope.

(a) This part sets forth the classification of cardiovascular devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 of this chapter cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, a cardiovascular device that has two or more types of uses (e.g., use both as a diagnostic device and as a therapeutic device) is listed in the subpart representing the more common use of the device, rather than in two or more subparts.

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the office of the Hearing Clerk, Food and Drug Administration.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6103 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1407]

MEDICAL DEVICES

Classification of Arrhythmia Detectors and Alarms

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying arrhythmia detectors and alarms into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device. Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of arrhythmia detectors and alarms:

1. Identification: An arrhythmia detector and alarm is a system that monitors the electrocardiogram (ECG) and is designed to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia, such as a premature contraction or ventricular fibrillation, exists.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the arrhythmia detector and alarm be classified into class III (premarket approval). Although the device is neither life-supporting nor life-sustaining, diagnostic information derived from the use of the device may be critical to proper management of the patient. If the algorithms used to detect various cardiac arrythmias are either inaccurate or inadequate, the resulting misdiagnosis can be life threatening. There is no consensus on the proper algorithms to be used in the device. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is insufficient information to establish a standard to provide such assurance. However, certain performance standards should apply to specific parts of this device. Because this device is attached to the body through conducting electrodes, its electrical characteristics, e.g., electrical leakage current, need to meet certain requirements. In addition, the device will require special labeling to inform the user of the accuracy, reproducibility, or limitations on the ability of the device to detect cardiac arrhythmias.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. The Panel believes that, although the device itself is not life supporting or sustaining, information derived from the device, if inaccurate, would create a potentially life-threatening situation. The Panel also believes that data do not exist showing the safety and efficacy of the device and that clinical trials are now the only method by which the safety and efficacy of the device can be established.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: Inadequate design of the ECG processing circuitry or program can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the arrhythmia detector and alarm be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for use in primary diagnosis of certain critical cardiac arrhythmias, and thus it is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because, if the device is used as a primary alarm system rather than as a supplement to the health care team, failure of the device may be fatal to the patient. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 by adding new Subpart B including new § 870.1025, as follows:

Subpart B—Cardiovascular Diagnostic Devices

§ 870.1025 Arrhythmia detector and alarm.

(a) *Identification.* An arrhythmia detector and alarm is a system that monitors the electrocardiogram and is designed to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia, such as a premature contraction or ventricular fibrillation, exists.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6104 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1408]

MEDICAL DEVICES

Classification of Blood Pressure Alarms

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood pressure alarms into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of blood pressure alarms:

1. Identification: A blood pressure alarm is a device that accepts the signal from a blood pressure transducer amplifier, processes the signal, and emits an alarm when the blood pressure falls outside a preset upper or lower limit.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the blood pressure alarm be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through a blood pressure transducer and a catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus, the electrical characteristics of this device, such as electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's performance characteristics, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the blood pressure alarm be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although blood pressure alarms are used both as diagnostic devices and as monitoring devices, they will be listed in the part of the Code of Federal Regulations for cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a) 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1100 as follows:

§ 870.1100 Blood pressure alarm.

(a) *Identification.* A blood pressure alarm is a device that accepts the signal from a blood pressure transducer amplifier, processes the signal, and emits an alarm when the blood pressure falls outside a pre-set upper or lower limit.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal.

Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6105 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1409]

MEDICAL DEVICES

Classification of Blood Pressure Computers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood pressure computers into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the General Hospital and Personal

Use Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of blood pressure computers:

1. Identification: A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that the blood pressure computer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through a blood pressure transducer amplifier and a catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health : (a) Misdiagnosis: if the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

Proposed Classification

The Commissioner agrees with the Panels' recommendations and is proposing that the blood pressure computer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although blood pressure computers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in subpart B by adding new § 870.1110 as follows:

§ 870.1110 Blood pressure computer.

(a) *Identification.* A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6106 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1410]

MEDICAL DEVICES

Classification of Blood Pressure Cuffs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood pressure cuffs into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic

Surgery Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of blood pressure cuffs:

1. Identification: A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that blood pressure cuffs be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the design of the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. The mechanical design and performance characteristics of the device should be maintained at a generally accepted satisfactory level. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue trauma: Overinflation, or use of an improper size cuff, can cause unnecessary tissue trauma. (b) Misdiagnosis: Inadequate design of cuff size can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendations and is proposing that the blood pressure cuff be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although blood pressure cuffs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding § 870.1120 as follows:

§ 870.1120 Blood pressure cuff.

(a) *Identification.* A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6107 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1411]

MEDICAL DEVICES

Classification of Noninvasive Blood Pressure Measurement Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying noninvasive blood pressure measurement systems into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel the Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonin-

vasive blood pressure measurement systems:

1. Identification: A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three can be derived through the use of transducers placed on the surface of the body.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that noninvasive blood pressure measurement systems be classified into class II because this device is neither life-supportng nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through surface transducers and can be electrically powered. It is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the design of the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. When functioning properly, the device emits an acceptable energy level into the body. Malfunction of the ultrasonic types of the device, however, may result in unsafe energy levels. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Cardiovascular Device Classification Panel cited three standards proposed by the medical community for blood pressure measurement equipment (Refs. 1 through 3).

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Tissue damage: In devices that use an ultrasonic detection method, excessive ultrasonic energy output can cause tissue damage. (c) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (d) Tissue ischemia: Any system that allows prolonged cuff inflation can cause tissue ischemia (deficiency of blood supply to a portion of the body).

Proposed Classification

The Commissioner agrees with the Panels' recommendations and is proposing that the noninvasive blood pressure measurement system be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although noninvasive blood pressure measurement systems are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Standardization of Blood Pressure Readings. Joint Recommendations of the American Heart Association and the Cardiac Society of Great Britain and Ireland." *American Heart Journal* 18:95-101, 1939.

2. Bordley, J., et al., "Recommendations for Human Blood Pressure Determinations by Sphygmomanometers." *Circulation*, 4:503-509, 1951.

3. Kirkendall, W. M., et al., "Recommendations for Human Blood Pressure Determinations by Sphygmomanometers," *Circulation*, 36:980-988, 1967.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1130 as follows:

§ 870.1130 Noninvasive blood pressure measurement system.

(a) *Identification.* A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three can be derived through the use of tranducers placed on the surface of the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6108 Filed 3-8-79 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1412]

MEDICAL DEVICES

Classification of Venous Blood Pressure Manometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying venous blood pressure manometers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II and the recommendation of the General and Plastic Surgery Device Classification Panel that the device be classified into class I. The effect of classifying a device into class II is to provide for the future development of one or more performance

standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification and the General and Plastic Surgery Device Classification Panels, FDA advisory committees, made the following recommendations with respect to the classification of venous blood pressure manometers:

1. Identification: A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

2. Recommended classification: The Cardiovascular Device Classification Panel recommends class II (performance standards) and recommends that establishing a performance standard for this device be a low priority. The General and Plastic Surgery Device Classification Panel recommends class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel recommends that venous blood pressure manometers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Cardiovascular Device Classification Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Cardiovascular Device Classification Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The General and Plastic Surgery Device Classification Panel believes that general controls would provide sufficient control over the performance characteristics of the device and listed no risks to health for the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Misdiagnosis: Inadequate design of calibration characteristics of the manometer can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Cardiovascular Device Classification Panel recommendation and is proposing that the venous blood pressure manometer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control misdiagnosis listed as a risk to health by the Cardiovascular Device Classification Panel. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although venous blood pressure manometers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1140 as follows:

§ 870.1140 Venous blood pressure manometer.

(a) *Identification.* A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6109 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1413]

MEDICAL DEVICES

Classification of diagnostic intravascular Catheters

AGENCY: Food and Drug Administration

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying diagnostic intravascular catheters into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurological Device Classification Panel, and the Radiological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of

the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation The Cardiovascular Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurological Device Classification Panel, and the Radiological Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of diagnostic intravascular catheters:

1. Identification: An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic group are right-heart catheters, left-heart catheters, and angiographic catheters, among others.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that intravascular diagnostic catheters be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The mechanical design of the device should also ensure adequate frequency response. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff, cardiac perforation and vessel dissection may result. (c) Misdiagnosis: Inadequate mechanical design with regard to frequency response can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the diagnostic intravascular catheter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because the device is more commonly used in cardiovascular catheterization procedures, the device will be listed in the Code of Federal Regulations under cardiovascular devices. Although diagnostic intravascular catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1200 as follows:

§ 870.1200 Diagnostic intravascular catheter.

(a) *Identification.* An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic group are right-heart catheters, left-heart catheters, and angiographic catheters, among others.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6110 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1414]

MEDICAL DEVICES

Classification of Continuous Flush Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying continuous flush catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments,

FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of continuous flush catheters:

1. Identification: A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the continuous flush catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the design of the device is inadequate for accurate and precise measurement of physiological functions through the catheter system, the resulting misdiagnosis could have a significant negative effect on the patient's health. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to keep the catheter free of clots without inhibiting the measurement of any physiological function, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (c) Tissue and blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood and tissue may result. (d) Gas embolism: If the infusion solution that flushes through the catheter is exhausted, a potentially debilitating or fatal gas embolism can escape into the bloodstream. (e) Hypervolemia: Overinfusion of the solution used to flush the catheter can lead to hypervolemia (abnormal increase in the blood plasma volume). (f) Misdiagnosis: Inadequate design with regard to possible degradation of the physiological waveform being measured can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the continuous flush catheter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although continuous flush catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1210 as follows:

§ 870.1210 **Continuous flush catheter.**

(a) *Identification.* A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6111 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1415]

MEDICAL DEVICES

Classification of Electrode Recording Catheters and Electrode Recording Probes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrode recording cath-

eters and electrode recording probes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electrode recording catheters and electrode recording probes:

1. Identification: Electrode recording catheters and electrode recording probes are devices used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The devices may be unipolar or multipolar for electrocardiogram detection, or may be a platinum tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that electrode recording catheters and electrode recording probes be classified into class II because these devices are neither life-supporting nor life-sustaining, but are potentially hazardous to life or health even when properly used. Because the devices are placed directly in contact with the bloodstream, they should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the devices should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The devices are used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of these devices. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of these devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of these devices and on their personal knowledge of, and experience with, these devices.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in these devices and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough or if the catheter is too stiff, cardiac perforation and vessel dissection may result. (c) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that electrode recording catheters and electrode recording probes be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of these devices. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of these devices. Although electrode recording catheters and electrode recording probes are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1120 as follows:

§ 870.1220 Electrode recording catheter and electrode recording probe.

(a) *Identification.* Electrode recording catheters and electrode recording probes are devices used to detect an intracardiac electrocardiogram, or to detect caridac output or left-to-right heart shunts. The device may be unipolar or multipolar for electrocardiogram detection, or may be a platinum tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Date: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6112 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1416]

MEDICAL DEVICES

Classification of Fiberoptic Oximeter Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fiberoptic oximeter catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class

II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fiberoptic oximeter catheters:

1. Identification: A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the fiberoptic oximeter catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The fiberoptic materials used in the device should allow the proper transmission of light energy to assure adequate diagnostic results from the system in which it is used. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: Inadequate design of the fiberoptic bundles can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (c) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (d) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the fiberoptic oximeter catheter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance to the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although fiberoptic oximeter catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1230 as follows

§ 870.1230 Fiberoptic oximeter catheter.

(a) *Identification.* A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner, for Regulatory Affairs.

[FR. Doc. 79- 6113 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1417]

MEDICAL DEVICES

Classification of Flow-Directed Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying flow-directed catheters into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation clas-

sifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of flow-directed catheters:

1. Identification: A flow-directed catheter is a device that incorporates a gas-filled balloon to help direct the catheter to the desired position.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that flow-directed catheters be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, that may affect the degree of compatibility. In addition, the material used for the balloon should not be excessively permeable to the filling gas, and the balloon burst strength should meet certain minimum requirements. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood campatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (c) Gas embolism: A rupture or a leak in the flow-directed catheter can allow potentially debilitating or fatal gas emboli to escape in the bloodstream.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendations and is proposing that the flow-directed catheter be classified into class II (performance standards). The Commission believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establih a standard to provide reasonable assurance of the safety and effectiveness of the device. Because the device is more commonly used in cardiovascular catheterization procedures, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although flow-directed catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1240 as follows:

§ 870.1240 Flow-directed catheters.

(a) *Identification.* A flow-directed catheter is a device that incorporates a gas-filled ballon to help direct the catheter to the desired position.

(b) *Classification.* Class II (Performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6114 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1418]

MEDICAL DEVICES

Classification of Percutaneous Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying percutaneous catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of percutaneous catheters:

1. Identification: a percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that percutaneous catheters be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the catheter which break or flake off may form potentially debilitating or fatal emboli.

(c) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the percutaneous catheter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although percutaneous catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1250 as follows:

§ 870.1250 Percutaneous catheter.

(a) *Identification.* A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6115 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1419]

MEDICAL DEVICES

Classification of pH Catheter Probes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pH catheter probes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pH catheter probes:

1. Identification: A pH catheter probe is a catheter with a special tip for measuring blood pH.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the pH catheter probe be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Certain performance characteristics of the pH catheter probe, such as electrical isolation, accuracy, and stability, should be maintained at an accepted level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (d) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pH catheter probe be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although pH catheter probes are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1260 as follows:

§ 870.1260 pH catheter probe.

(a) *Identification.* A pH catheter probe is a catheter with a special tip for measuring blood pH.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m., and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6116 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1420]

MEDICAL DEVICES

Classification of Intracavitary Phono-Catheter Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposd regulation classifying intracavitary phono-catheter systems into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (FHA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intracavitary phono-catheter systems:

1. Identification: An intracavitary phono-catheter system is a system that includes a catheter with an acoustic transducer and the associated device that processes the signal from the transducer; this device records bioacoustic phenomena from a trans-

ducer placed within the heart, blood vessels, or body cavities.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the intracavitary phono-catheter system be classified into class II (performance standards) because this device is neither life-supporting nor lifesustaining but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The acoustic transducer has performance characteristics such as electrical isolation, accuracy, and stability that should be maintained at an acceptable level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage currrent can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (d) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (e) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the intracavitary phonocatheter system be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although intracavitary phono-catheter systems are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1270 as follows:

§ 870.1270 Intracavitary phono-catheter system.

(a) *Identification.* An intracavitary phono-catheter system is a system that includes a catheter with an acoustic transducer and the associated device that processes the signal from the transducer; this device records bioacoustic phenomena from a transducer placed within the heart, blood vessels, or body cavities.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6117 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1421]

MEDICAL DEVICES

Classification of Steerable Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying steerable catheters into class II (performace standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER, provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classfication Panel, an FDA advisory committee, made the following recommendation with respect to the classification of steerable catheters:

1. Identification: A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the steerable catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The devise is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (c) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the steerable catheter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although steerable catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1280 as follows:

§ 870.1280 Steerable catheter.

(a) *Identification.* A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR. Doc. 79- 6118 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1422]

MEDICAL DEVICES

Classification of Steerable Catheter Control Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying steerable catheter control systems into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of steerable catheter control systems:

1. Identification: A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the steerable catheter control system be classified into class II because this device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health even when properly used. If the mechanical design of the device is inadequate for proper steering of a catheter, use of the device could result in cardiac perforation or vessel dissection. Performance characteristics, including any limitations on the device's

mechanical ability to steer a catheter, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac perforation and vessel dissection: If the mechanical design of the device does not properly control the motion of the catheter to which the device is attached, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the steerable catheter control system be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although steerable catheter control systems are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1290 as follows:

§ 870.1290 Steerable catheter control system.

(a) *Identification.* A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6119 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1423]

MEDICAL DEVICES

Classification of Catheter Cannulas

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter cannulas into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter cannulas:

1. Identification: A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the catheter cannula be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Tissue and blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood and tissue may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter cannula be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although catheter cannulas are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1300 as follows:

§ 870.1300 Catheter cannula.

(a) *Identification.* A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m, Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6120 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1424]

MEDICAL DEVICES

Classification of Vessel Dilators for Percutaneous Catheterization

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vessel dilators for percutaneous catheterization into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of is publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Caradiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vessel dilators for percutaneous catheterization:

1. Identification: A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.

2. Recommended classification: Class II (performance standards): The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The panel recommends that the vessel dilator for percutaneous catheterization be classified into class II because this device is neither life-sustaining nor life-supporting, but is potentialy hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood campatibility, including requirements for adequate surface finish and cleanliness which may affect the degree of compatibility. The mechanical design of the device should enable it to perform its function of enlarging the opening into the vessel with a minimum of tissue damage and without causing vessel dissection. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Vessel dissection: If the dilator is rough, or if the dilator is too stiff, vessel dissection may result. (b) Embolism: Pieces of the dilator which break or flake off may form potentially debilitating or fatal emboli.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vessel dilator for percutaneous catheterization be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Although the vessel dilator for percutaneous catherization is used both as a diagnostic device and as a monitoring device, it will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in subpart B by adding new § 870.1310 as follows:

§ 870.1310 Vessel dilator for percutaneous catheterization.

(a) *Identification.* A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6121 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1425]

MEDICAL DEVICES

Classification of Catheter Guide Holders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter guide holders into class I (ageneral controls). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter guide holders:

1. Identification: A catheter guide holder is a tube that holds a spring guide during percutaneous terchniques and during storage and sterilization.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the catheter guide holder be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is a simple tube which is not life sustaining, life supporting, or implanted and which is not potentially hazardous to life and health when properly used. The Panel believes that the materials currently used in the device are generally acceptable and need no additional control requirements.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the lack of potential hazards associated with the inherent properties of the device and on their personal knowledge of, and eperience with, the device.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter guide holder be classified into class I (general controls). The Commissioner believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1320 as folllows:

§ 870.1320 Catheter guide holder.

(a) *Identification.* A catheter guide holder is a tube that holds a spring guide during percutaneous techniques and during storage and sterilization.

(b) *Classification.* Class I (general controls.)

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 19679.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs

[FR Doc. 79-79-6122 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1426]

MEDICAL DEVICES

Classification of Catheter Guide Wires

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter guide wires into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel and the Radiological Device Classification Panel that the device be classified into class II, and the recommendation of the Neur-

ogical Device Classification Panel that the device be classified into class I. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the Neurological Device Classification Panel, and the Radiological Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of catheter guide wires:

1. Identification: A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

2. Recommended classification: Class II (performance standards). The Cardiovascular Device Classification Panel and the Radiological Device Classification Panel recommend that establishing a performance standard for this device be a high priority. The Neurological Device Classification Panel recommends Class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel and the Radiological Device Classification Panel recommend that the catheter guide wire be classified into class II because this device is neither life-supporting nor life sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Neurological Device Classification Panel believes that the device presents no potential hazard to health and that general controls are sufficient to control the safety and effectiveness of the device and recommends classifying the device into class I (general controls).

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (c) Cardiac perforation and vessel dissection: If the guide wire is rough or too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendations of the Cardiovascular Device Classification Panel and the Radiological Device classification Panel and is proposing that the catheter guide wire be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control thromboembolism, embolism, or cardiac perforation and vessel dissection listed as risks to health by the Panels. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although guide wires are used in many different catheterization procedures, this device will be listed in the Code of Federal Regulations under cardiovascular devices because cardiovascular uses are more common.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1330 as follows:

§ 870.1330 Catheter guide wire.

(a) *Identification.* A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6123 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1427]

MEDICAL DEVICES

Classification of Catheter Percutaneous Introducers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter percutaneous introducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation clas-

sifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter percutaneous introducers:

1. Identification: A catheter percutaneous introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.

2. Recommended classification: Class II (performance standards). The panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the catheter percutaneous introducer be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, or maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the introducer which break or flake off may form potentially debilitating or fatal emboli. (c) Vessel dissection: If the introducer or its tip is rough, or if the introducer is improperly designed, vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter percutaneous introducer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonalbe assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because catheter percutaneous introducers are used as an accessory device to catheters, this device will be listed along with catheters in the Code of Federal Regulations under cardiovascular diagnostic devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1340 as follows:

§ 870.1340 Catheter percutaneous introducer.

(a) *Identification.* A catheter percutaneous introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6124 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1428]

MEDICAL DEVICES

Classification of Catheter Balloon Repair Kits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter balloon repair kits into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter balloon repair kits:

1. Identification: A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the catheter balloon repair kit be classified into class III because the device presents a potential unreasonable risk of illness or injury. If the device fails to adequately repair a damaged balloon catheter, gas or particulate embolism is likely to occur which may present a substantial risk to health that is possibly debilitating or fatal. The Panel believes that these devices do not perform adequately. In addition, the Panel believes that sufficient data do not exist to establish adequate standards to provide reasonable assurance of the safety and effectiveness of the balloon repair kit, and that general controls alone would not provie sufficient control over the performance characteristics of this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. The Panel is not aware of any published literature on this device.

5. Risks to health: (a) Gas embolism: Balloon rupture caused by the repair material or a leak in the repair material can allow potentially debilitating or fatal gas emboli to escape into the bloodstream. (b) Embolism: Pieces of the balloon that break or flake off may form potentially debilitating or fatal emboli. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli. (d) Cardiac arrhythmias: Toxic substances released from the repair material (glue or other adhesive) can trigger cardiac arrhythmias (irregularities in heart rhythm).

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the catheter balloon repair kit be classified into class III (premarket approval). The Commissioner believes the device presents a potential unreasonable risk of illness or injury because potentially debilitating or fatal gas or particulate emboli are likely to occur when this device is used. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1350 as follows:

§ 870.1350 Catheter balloon repair kit.

(a) *Identification.* A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6125 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1429]

MEDICAL DEVICES

Classification of Trace Microsphere

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying trace microspheres into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of trace microspheres:

1. Identification: A trace microsphere is a radioactively tagged nonbiodegradable particle that is injected into an artery or vein and trapped in the capillary bed for the purpose of studying blood flow within or to an organ.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the trace microsphere be classified into class III because this implanted device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even

when properly used, and because there are insufficient data to establish the safety and effectiveness of the device. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to demonstrate blood flow should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility. The device could cause genetic damage by exposing the patient's reproductive organs to excessive radiation. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in the device may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: If the microspheres are too large or tend to clump together, they can lodge in a blood vessel and block the flow of blood to an organ. (c) Tissue damage: Tissue damage can result from excessive radioactivity of the particles.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the trace microsphere be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (diagnosis of blood flow disorders) which is of substantial importance in preventing impairment of human health. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1360 as follows:

§ 870.1360 Trace microsphere.

(a) *Identification.* A trace microsphere is a radioactively tagged nonbiodegradable particle that is intended to be injected into an artery or vein and trapped in the capillary bed for the purpose of studying blood flow within or to an organ.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6126 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No.78N-1430]

MEDICAL DEVICES

Classification of Catheter Tip Occluders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter tip occluders into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of catheter tip occluders:

1. Identification: A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the cathether tip occluder be classified into class II because this device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness which may affect the degree of compatibility. The device should fit properly in the catheter in which it is used to avoid potential vessel perforation. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient

information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Cardiac perforation and vessel dissection: If the device is too small for the catheter in which it is used, it could protrude from the proximal end of the catheter and cause cardiac perforation and vessel dissection.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter tip occluder be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1370 as follows:

§ 870.1370 Catheter tip occluder.

(a) *Identification.* A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6127 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1431]

MEDICAL DEVICES

Classification of Catheter Stylets

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter stylets into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 18, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter stylets:

1. Identification: A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the catheter stylet be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experices with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Cardiac perforation and vessel dissection: If the stylet is rough or too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter stylet be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under au-

thority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1380 as follows:

§ 870.1380 Catheter stylet.

(a) *Identification.* A catheter stylet is a wire that is run through a catheter or cannual to render it stiff.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Recieved comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6128 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1432]

MEDICAL DEVICES

Classification of Trocars

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying trocars into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II, and the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drug proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides backgroud information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of trocars:

1. Identification: A trocar is a sharp-pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.

2. Recommended classification: The Cardiovascular Device Classification Panel recommends that this device be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Neurological Device Classification Panel recommends that this device be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel recommends that the trocar be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reaction. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness which may affect the degree of compatibility. If the device is not properly designed it can cause excessive damage to the vessel in which it is used. The Cardiovascular Device Classification Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Cardiovascular Device Classification Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Neurological Device Classification Panel reviewed needles used to puncture the artery prior to catheterization for cerebral angiograms. These needles are essentially the same device, and serve the same function, as the trocar for cardiovascular catherterization procedures. The Neurological Device Classification Panel believes that the device presents no potential hazard to health and that general controls are sufficient to ensure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Unnecessary damage to vessel: Improper mechanical design of the device can cause unnecessary damage to the vessel during the piercing operation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Cardiovascular Device Classification Panel's recommendation and is proposing that the trocar be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control unnecessary damage to vessels listed as a risk to health by the Cardiovascular Device Classification Panel. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although trocars are used in many different catheterization procedures, this device will be listed in the Code of Federal Regulations under cardiovascular devices because cardiovascular uses are more common.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1390 as follows:

§ 870.1390 Trocar.

(a) *Identification.* A trocar is a sharp-pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6129 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No.78-1433]

MEDICAL DEVICES

Classification of Programmable Diagnostic Computers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying programmable diagnostic computers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of programmable diagnostic computers:

1. Identification: A programmable diagnostic computer is a device that can be programmed to compute various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices; this device includes any associated commercially supplied programs.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the programmable diagnostic computer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through transducers, electrodes, or catheters and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy and reproducibility, and any limitations on the device's programmed measurements, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electric shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical prodedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the programmable diagnostic computer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although programmable diagnostic computers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1425 as follows:

§ 870.1425 Programmable diagnostic computer.

(a) *Identification.* A programmable diagnostic computer is a device that can be programmed to compute various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices; this device includes any associated commercially supplied programs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be

submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6130 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1434]

MEDICAL DEVICES

Classification of Single-Function, Preprogrammed Diagnostic Computers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying single-function, preprogrammed diagnostic computers into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of single-function, preprogrammed diagnostic computers:

1. Identification: A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow parameter based on information obtained from one or more electrodes, transducers, or measuring devices.

2. Recommended classification: Class II (performance standards). The Panel recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommends that the single-function, preprogrammed diagnostic computer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through transducers, electrodes, or catheters and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's preprogrammed function, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The recommendation of the General and Plastic Surgery Device Classification Panel relates specifically to cardiac output computers, while the Cardiovascular Device Classification Panel makes its recommendation or diagnostic computers of any cardiovascular parameter. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias, Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the single-function, preprogrammed diagnostic computer be classified into class II performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standards would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because the device is used in general cardiovascular diagnosis and monitoring, the device will be listed in the Code of Federal Regulations under cardiovascular devices. Although single-function, preprogrammed diagnostic computers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 300c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1435 as follows:

§870.1435 Single-function, preprogrammed diagnostic computer.

(a) *Identification.* A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow parameter based on information obtained from one or more electrodes, transducers, or measuring devices.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6131 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1435]

MEDICAL DEVICES

Classification of Densitometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying densitometers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Devise Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of densitometers:

1. Identification: A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the densitometer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining but is potentially hazardous to life and health even when properly used. This device is placed inline between a catheter and a withdrawal-infusion pump and, in that position, continuously measures optical density, from which cardiac output may be determined. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of cardiac output, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

(b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physican may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the densitometer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectivess of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, and Drug and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1450 as follows:

§ 870.1450 Densitometer.

(a) *Identification.* A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.

(b) *Classification.* Class II (performance standards).

Interested persons, may, on or before May 8, 1979 submit to the Hearing Clerk (HFA—305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6132 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1436]

MEDICAL DEVICES

Classification of Angiographic Injectors and Syringes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying angiographic injectors and syringes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of angiographic injectors and syringes:

1. Identification: An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the angiographic injector and syringe be classified in to class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's injection pressure and rate of injection, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. When the device is synchronized with the ECG signal, proper timing of the injection is another important characteristic which should be controlled. Electrical leakage current is also a problem because the device is connected directly to the blood stream via a catheter. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to estabish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure and this may lead to iatrogenic complications. (b) Intramyocardial injection: If the pressure control is not accurate or does not properly limit the injection pressure, myocardial damage can result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the angiographic injector and syringe be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1650 as follows:

§ 870.1650 Angiographic injector and syringe.

(a) *Identification.* An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner, for Regulatory Affairs.

[FR Doc. 79-6133 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No.78-1437]

MEDICAL DEVICES

Classification of Indicator Injectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying indicator injectors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device

Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of indicator injectors:

1. Identification: An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the blood stream. This device may be used in conjunction with a densitometer or thermodilution device to determine cardiac output.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that indicator injectors be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through a catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy and reproducibility, and any limitations on the device's injection pressure and rate of injection, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the indicator injector be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C.360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1660 as follows:

§ 870.1660 Indicator injector.

(a) *Identification.* An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the blood stream. This device may be used in conjunction with a densitometer or thermodilution device to determine cardiac output.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6134 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1438]

MEDICAL DEVICES

Classification of Syringe Actuators for Injectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying syringe actuators for injectors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305). Food and Drug Administration, Rm. 4-65, 6500 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450). Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7759.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of syringe actuators for injectors:

1. Identification. A syringe actuator for injectors is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph (ECG) signal.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the syringe actuator for injectors be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through ECG electrode leads and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. In addition, this device must properly sense the ECG and synchronize the injection to the correct portion of the heart cycle. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. Performance characteristics, including accuracy, reproducibility, and any limitations in the device's sensing of the ECG and synchronizing of the injection, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Failure of the device to properly synchronize the injection with the correct time in the cardiac cycle may also lead to cardiac arrythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the syringe actuator for injectors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1670 as follows:

§ 870.1670 Syringe actuator for injectors.

(a) *Identification.* A syringe actuator for injectors is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6135 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1439]

MEDICAL DEVICES

Classification of External Programmable Pacemaker Pulse Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external programmable pacemaker pulse generators into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommenda-

tion with respect to the classification of external programmable pacemaker pulse generators:

1. Identification: An external programmable pacemaker pulse generator is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that external programmable pacemaker pulse generators be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to stimulate, or stimulates improperly, serious cardiac sequelae can occur. This device is attached to the body through stimulating electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Although the device releases an acceptable level of electrical energy into the body when functioning properly, unsafe energy levels may be released if the device malfunctions. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to stimulate the heart, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Failure to stimulate: An electronic circuit malfunction could cause failure to stimulate. (b) Improper stimulation: Improper sensing of the electrical activity of the heart, or electromagnetic interference from other sources, could lead to improper stimulation. Inaccurate rate control or electronic circuit failure could cause improper stimulation rate. (c) Cardiac arrythmias: A sensing failure resulting in excess electrical leakage current or stimulation of the heart during the vulnerable period of the cardiac cycle could cause cardiac arrythmias.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the external programmable pacemaker pulse generator be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although external programmable pacemaker pulse generators are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1750 as follows:

§ 870.1750 External programmable pacemaker pulse generator.

(a) *Identification.* An external programmable pacemaker pulse generator is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal.

Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6136 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1440]

MEDICAL DEVICES

Classification of Withdrawal-Infusion Pumps

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying withdrawal-infusion pumps into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of withdrawal-infusion pumps:

1. Identification: A withdrawal-infusion pump is a device designed to inject accurately medications into the

bloodstream and to withdraw blood samples for use in determining cardiac output.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Although withdrawal-infusion pumps can be life-supporting and life-sustaining, the Panel recommends that this device be classified into Class II. This device is attached to the body through an intravascular catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of fluid volume delivery or withdrawal, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel reviewed the "Final Report: Safety and Performance of Angiographic Injectors and Infusion and Withdrawal Pumps," of June 30, 1977, prepared under contract for FDA by the Utah Biomedical Testing Laboratory. This report cites four types of infusion and withdrawal pumps, including this device. The report states that the performance required of a withdrawal-infusion pump is the delivery (or withdrawal) of fluid to (or from) the patient in an accurate, controllable manner, without inadvertent administration of substances not intended to be delivered (e.g., air or electrical energy). The report shows that standards can be established for these characteristics.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Inaccurate administration of drugs: An inaccurate pump speed control can produce an overdosage or underdosage of a drug. (c) Inaccurate determination of the patient's cardiac output: Inaccurate pump speed control can also result in inaccurate determination of cardiac output.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the withdrawal-infusion pump be classified into class II (performance standards). Although the device can be life-supporting, the Commissioner believes that a performance standard is sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner believes that general controls by themselves are insufficient to control the risks to health of the device. Although withdrawal-infusion pumps are used both as diagnostic devices and as therapeutic devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1800 as follows:

§ 870.1800 Withdrawal-infusion pump.

(a) *Identification.* A withdrawal-infusion pump is a device designed to inject accurately medications into the bloodstream and to withdraw blood samples for use in determining cardiac output.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6137 Filed 3-8-79; 8:45 am]

[1110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1441]

MEDICAL DEVICES

Classification of Stethoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying stethoscopes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II and the recommendations of the General Hospital and Personal Use Device Classification Panel and the General and Plastic Surgery Device. Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performace standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450, Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification

Panel, and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of stethoscopes:

1. Identification: A stethoscope is a mechanical or electrically amplified device used to project the sounds associated with the heart, arteries, and veins.

2. Recommended classification: The Cardiovascular Device Classification Panel recommends that the stethoscope be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The General Hospital and Personal Use Device Classification Panel and the General and Plastic Surgery Device Classification Panel recommend that stethoscopes be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel recommends that the stethoscope be classified into class II because this device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. This device is used routinely in a wide variety of diagnostic medical procedures. Performance characteristics, including adequate frequency response, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The General and Plastic Surgery Device Classification Panel and the General Hospital and Personal Use Device Classification Panel believe that the device presents no potential hazards to life or health and that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Misdiagnosis: Inadequate design with regard to frequency response can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendation of the Cardiovascular Device Classification Panel and is proposing that the stethoscope be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control misdiagnosis listed as a risk to health by the Cardiovascular Device Classification Panel. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although stethoscopes have many uses, this device will be listed in the Code of Federal Regulations under cardiovascular devices because cardiovascular uses are the most common.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1875 as follows:

§870.1875 Stethoscope.

(a) *Identification.* A stethoscope is a mechanical or electrically amplified device used to project the sounds associated with the heart, arteries, and veins.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6138 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1442]

MEDICAL DEVICES

Classification of Thermodilution Probes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying thermodilution probes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305). Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450). Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7759.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of therodilution probes:

1. Identification: A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendations: The Panel recommends that thermodilution probes be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of cardiac output, the resulting misdiagnosis could have a significant negative effect on the patient's health. Because the device is place directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatability, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatiblity. This device is attached to the body directed or through a catheter and is used in a clinical environement where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of cardiac output, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be used hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safely and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: Inadequate design with regard to resistance change in the device or the device's accuracy can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the thermodilution probe be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1915 as follows:

§ 870.1915 **Thermodilution probe.**

(a) *Identification.* A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6139 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1443]

MEDICAL DEVICES

Classification of Biopotential Amplifier and Signal Conditioners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying biopotential amplifiers and signal conditioners into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of biopotential amplifiers and signal conditioners:

1. Identification: A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a

performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that biopotential amplifiers and signal conditioners be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the amplification and conditioning are inadequate for accurate and precise measurement of the bioelectric signal, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, stability, frequency response, input impedance, and any limitations on the device's electrical design, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: Inadequate design with regard to frequency response and accuracy and stability of zero and calibration can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the biopotential amplifier and signal conditioner be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although biopotential amplifiers and signal conditioners are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 by adding new Subpart C and new § 870.2050 as follows:

Subpart C—Cardiovascular Monitoring Devices

§ 870.2050 Biopotential amplifier and signal conditioner.

(a) *Identification.* A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6140 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1444]

MEDICAL DEVICES

Classification of Transducer Signal Amplifiers and Conditioners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transducer signal amplifiers and conditioners into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendation on the classification of transducer signal amplifiers and conditioners:

1. Identification: A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or

condition the signal emitted by the transducer.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that the transducer signal amplifiers and conditioners be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If signal amplification and conditioning are inadequate for accurate and precise measurement of a physiological function, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through transducers and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproductibility, and any limitations on the device's electrical design should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectivenes of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the device provides an inadequate frequency response, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the panels' recommendations and is proposing that the transducer signal amplifier and conditioner be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because the transducer signal amplifier and signal conditioner is used to measure many cardiovascular functions, and because the recommendation of the Anesthesiology Device Classification Panel deals with the measurement of blood pressure, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although transducer signal amplifiers and conditioners are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2060 as follows:

§ 870.2060 Transducer signal amplifier and conditioner.

(a) *Identification.* A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or condition the signal emitted by the transducer.

Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6141 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1445]

MEDICAL DEVICES

Classification of Cardiovascular Blood Flowmeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiovascular blood flowmeters into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, and the Anesthesiology Device Classification Panel, the Gastroenterology and Urology Device Classification Panel, the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the de-

velopment of the proposed regulation. The Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, the Gastroenterology and Urology Device Classification Panel, and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of cardiovascular blood flowmeters:

1. Identification: A cardiovascular blood flowmeter is a device, connected to a flow transducer, that energizes the transducer and processes and displays the blood flow signal.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that blood flowmeters be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood flow, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through a flow transducer and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Although the device releases an acceptable energy level into the body when functioning properly, unsafe energy levels may be released if the device malfunctions. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood flow, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue and blood damage: If the device is not designed properly, ultrasonic energy can be released into the body at levels that can damage tissue and blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the cardiovascular blood flowmeter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood flow is an indicator of cardiovascular function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although cardiovascular blood flowmeters are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2100 as follows:

§ 870.2100 Cardiovascular blood flowmeter.

(a) *Identification.* A cardiovascular blood flowmeter is a device that is connected to a flow transducer that energizes the transducer and processes and displays the blood flow signal.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs

[FR Doc. 79-6142 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1446]

MEDICAL DEVICES

Classification of Extravascular Blood Flow Probes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying extravascular blood flow probes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rabmoeller, Bureau of Medical Device (HFK-450), Food and Drug Administration, Depart-

ment of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendation regarding classification of extravascular blood flow probes:

1. Identification: An extravascular blood flow probe is an extravascular ultrasonic or electromagentic probe used in conjunction with a blood flowmeter to measure blood flow in a chamber or vessel.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that extravascular blood flow probes be classifed into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise blood flow measurement, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through the skin or the exterior surface of the blood vessels and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's blood flow measurement, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catherterization or surgical procedure, and this may lead to iatrogenic complications. (b) Tissue and blood damage: If the device is not properly designed, excessive energy can be released into the body at levels that can damage tissue and blood. (c) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the extravascular blood flow probe be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because the measurement of blood flow is an indicator of cardiovascular function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although extravascular blood flow probes are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2120 as follows:

§ 870.2120 Extravascular blood flow probe.

(a) *Identification.* An extravascular blood flow probe is an extravascular ultrasonic or electromagnetic probe used in conjunction with a blood flowmeter to measure blood flow in a chamber or vessel.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6143 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1447]

MEDICAL DEVICES

Classification of Cardiac Monitors (Including Cardiotachometers and Rate Alarms)

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiac monitors (including cardiotachometers and rate alarms) into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs

proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendation regarding classification of cardiac monitors (including cardiotachometers and rate alarms):

1. Identification: A cardiac monitor (including a cardiotachometer and a rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that cardiac monitors be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Failure of the device to accurately measure heart rate can result in misdiagnosis that could have a significant negative effect on the patient's health. This device is attached to the body through a series of amplifiers, transducers, or electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of heart rate, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the processing circuitry is inadequate, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the cardiac monitor (including a cardiotachometer and rate alarm) be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because cardiac monitoring indicates heart function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although cardiac monitors (including cardiotachometers and rate alarms) are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2300 as follows:

§ 870.2300 Cardiac monitor (including a cardiotachometer and a rate alarm).

(a) *Identification.* A cardiac monitor (including a cardiotachometer and a rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6144 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1448]

Medical Devices

Classification of Apex Cardiographs (Vibrocardiographs)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying apex cardiographs (vibrocardiographs) into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more

performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of apex cardiographs (vibrocardiographs):

1. Identification: An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that apex cardiographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of the heart motion, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through a transducer and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of the heart motion should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the apex cardiograph (vibrocardiograph) be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although apex cardiographs (vibrocardiographs) are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2310 as follows:

§ 870.2310 Apex cardiograph (vibrocardiograph).

(a) *Identification.* An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visusl display of the motion of the heart; this device also provides any excitation energy required by the transducer.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6145 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1449]

MEDICAL DEVICES

Classification of Ballistocardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ballistocardiographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs

proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305). Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides backgound information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ballistocardiographs:

1. Identification: A ballistocardiograph is a device, including a supporting structure on which the patient is place, that moves in response to blood ejection from the heart. The device often provides a visual display.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the ballistocardiograph be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to accurately measure cardiac function, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device directly supports the whole body of the patient and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of cardiac function, should be maintained at a generally accepted satisfactory level should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can distrub the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ballistocardiograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although ballistocardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2320 as follows:

§ 870.2320 Ballistocardiograph.

(a) *Identification.* A ballistocardiograph is a device, including a supporting structure on which the patient is placed, that moves in response to blood ejection from the heart. The device often provides a visual display.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6146 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1450]

MEDICAL DEVICES

Classification of Echocardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying echocardiographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of echocardiographs:

1. Identification: An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that echocardiographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise imaging of cardiovascular structures, resulting misinterpretations could have a significant negative effect on the patient's health. This device is attached to the body through an ultrasonic transducer which, when functioning normally, releases an acceptable energy level into the body. Malfunction of the device, however, may result in the emission of unsafe energy levels. In addition, the device is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, such as electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to image cardiovascular structures, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue and blood damage: If the device is not designed properly, ultrasonic energy can be released into the body at levels that can damage tissue and blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the echocardiograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although echocardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2330 as follows:

§ 870.2330 Echocardiograph.

(a) *Identification.* An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6147 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1451]

MEDICAL DEVICES

Classification of Electrocardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrocardiographs into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, and the General and Plastic Surgery Device Classifica-

tion Panel, FDA advisory committees, made the following recommendations with respect to the classification of electrocardiographs (ECG's):

1. Identification: An electrocardiograph is a device used to process the electrical signal transmitted through two or more ECG electrodes and to produce a visual display of the electrical signal produced by the heart.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that the electrocardiograph be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of the electrical activity of the heart, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through ECG electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of the electrical activity of the heart, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Cardiovascular Device Classification Panel referred to the American Heart Association recommendations for performance characteristics of electrocardiographs. (*Circulation*, 35:583-602, 1967.)

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response of the device is inadequate, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the electrocardiograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard wou'd provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because ECG's measure the electrical characteristics of the heart, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although electrocardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2340 as follows:

§ 870.2340 Electrocardiograph.

(a) *Identification.* An electrocardiograph is a device used to process the electrical signal transmitted through two or more ECG electrodes and to produce a visual display of the electrical signal produced by the heart.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6148 Filed 3-8-79;8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1452]

MEDICAL DEVICES

Classification of Electrocardiograph Lead Switching Adaptors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrocardiograph lead switching adaptors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides back-

ground information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electrocardiograph (ECG) lead switching adaptors:

1. Identification: An electrocardiograph lead switching adaptor is a passive switching device to which ECG limb and chest leads may be attached. This device is used to connect various combinations of limb and chest leads to the output terminals in order to create standard lead combinations such as leads I, II, and III.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ECG lead switching adaptors be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is designed so that it improperly connects the ECG leads, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through ECG electrodes and is used in a clinical environment where excessive leakage current can be a serious harzard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics involving the design of the switching adaptor should be maintained at a generally accepted satisfactory level. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: Improper design of the switching adaptor and lack of standardization of the leads can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Cardiac arrhythmias or electrical shock: Proper electrical isolation of the ECG leads by the device is necessary to prevent excessive electrical leakage current, which can disturb the normal electrophysiology of the heart and lead to the onset of cardiac arrhythmias.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the electrocardiograph lead switching adaptor be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although electrocardiograph lead switching adaptors are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2350 as follows:

§ 870.2350 Electrocardiograph lead switching adaptor.

(a) *Identification.* An electrocardiograph lead switching adaptor is a passive switching device to which ECG limb and chest leads may be attached. This device is used to connect various combinations of limb and chest leads to the output terminals in order to create standard lead combinations such as leads I, II, and III.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6149 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1453]

MEDICAL DEVICES

Classification of Electrocardiograph Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrocardiograph electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electrocardiograph electrodes:

1. Identification: An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that electrocardiograph electrodes be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to transmit accurately the electrical signal produced by the heart, the resulting misdiagnosis could have a significant negative effect upon the patient's health. Because the device is in direct contact with the skin, the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. Performance characteristics involving the device's ability to sense and transmit the electrical signal should also be maintained at a generally accepted satisfactory level. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device.The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Skin irritation: Irritants in the materials of which the device is made can lead to skin irritation. (b) Misdiagnosis: An improper electrode-medium combination creating an excessively high impedance, or a device design which allows excessive interference from subject movement, can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the electrocardiograph electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although electrocardiograph electrodes are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2360 as follows:

§ 870.2360 Electrocardiograph electrode.

(a) *Identification.* An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6150 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1454]

MEDICAL DEVICES

Classification of ECG Surface Electrode Testers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation clasifying electrocardiograph (ECG) surface elecrode testers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of ECG surface elecrode testers:

1. Identification: An electrocardiograph surface electrode tester is a device used to test the function and application of ECG electrodes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the ECG surface electrode tester be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through ECG electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the device is inadequate for accurate and precise indication of ECG electrode function, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to test ECG electrodes, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ECG surface electrode tester be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The ECG surface electrode tester will be listed in the Code of Federal Regulations (CFR) under cardiovascular monitoring devices because the device is an accessory to ECG electrodes which are listed in the CFR under cardiovascular monitoring devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2370 as follows:

§ 870.2370 ECG surface electrode tester.

(a) *Identification.* An electrocardiograph surface electrode tester is a device used to test the function and application of ECG electrodes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6151 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1455]

MEDICAL DEVICES

Classification of Electrocardiograph Conducting Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrocardiograph conducting media into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electrocardiograph conducting media:

1. Identification: Electrocardiograph conducting medium is the conductive paste or jelly that is applied to the surface of the body to trasmit the electrical signal at the body surface to the electrocardiograph (ECG) electrode.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priorty.

3. Summary of reasons for recommendation: The Panel recommends that electrocardiograph conducting media be classified into class II because this device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. Because the device is in direct contact with the skin, the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. Performance characteristics involving the device's ability to transmit the electrical signal and the devices's compatibility with the electrocardiograph electrode should be maintained at a generally accepted satisfactory level.

The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Skin irritation: Irritants in the materials used in this device can lead to skin irritation. (b) Misdiagnosis: An improper electrode-medium combination creating an excessively high impedance can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the electrocardiograph conducting media be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although electrocardiograph conducting media are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2380 as follows:

§ 870.2380 Electrocardiograph conducting medium.

(a) *Identification.* Electrocardiograph conducting medium is the conductive paste or jelly that is applied to the surface of the body to transmit the electrical signal at the body surface to the electrocardiograph (ECG) electrode.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6152 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1456]

MEDICAL DEVICES

Classification of Phonocardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying phonocardiographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commission of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of phonocardiographs:

1. Identification: A phonocardiograph is a device used to amplify or condition the signal from a heart sound transducer. This device furnishes the excitation energy for the transducer and provides a visual or audible display of the heart sounds.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that phonocardiographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of heart sounds, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through a heart sound transducer and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of heart sounds, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation

on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the phonocardiograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although phonocardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2390 as follows:

§ 870.2390 Phonocardiograph.

(a) *Identification.* A phonocardiograph is a device used to amplify or condition the signal from a heart sound transducer. This device furnishes the excitation energy for the transducer and provides a visual or audible display of the heart sounds.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6153 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1457]

MEDICAL DEVICES

Classification of Vectorcardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vectorcardiographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vectorcardiographs:

1. Identification: A vectorcardiograph: is a device used to process the electrical signal transmitted through ECG electrodes and to produce a visual display of the magnitude and direction of the electrical signal produced by the heart.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that vectorcardiographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of the electrical activity of the heart, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through ECG electrodes and is used in a clinical enviroment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics including accuracy, reproducibility, and any limitations on the device's measurement of the electrical activity of the heart, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of car-

diac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response is inadequate, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vectorcardiograph be classifed into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although vectorcardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the part of the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal, Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2400 as follows:

§ 870.2400 Vectorcardiograph.

(a) *Identification.* A Vectorcardiograph is a device used to process the electrical signal transmitted through ECG electrodes and to produce a visual display of the magnitude and direction of the electrical signal produced by the heart.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6154 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1458]

MEDICAL DEVICES

Classification of Medical Cathode-Ray Tube Displays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying medical cathode-ray tube displays into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of medical cathode-ray tube displays:

1. Identification: A medical cathode-ray tube display is a device designed primarily to display selected biological signals. This device often incorporates special display features unique to a specific biological signal.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that medical cathode-ray tube displays be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise display of a designated physiological signal, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through catheters, transducers, electrodes, and amplifiers and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's display of physiological signals, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provided sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties, of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or the frequency response is indequate, the device may generate inaccu-

rate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the medical cathode-ray tube display be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although medical cathode-ray tube displays are used both as diagnostic devices and as monitoring devices, they will be listed in the part of the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2450 as follows:

§ 870.2450 Medical cathode-ray tube display.

(a) *Identification.* A medical cathode-ray tube display is a device designed primarily to display selected biological signals. This device offen incorporates special display features unique to a specific biological signal.

Classification. Class II (performance standards).

Intrested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6155 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1459]

MEDICAL DEVICES

Classification of Signal Isolation Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying signal isolation systems into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of signal isolation systems:

1. Identification: A signal isolation system is a device that electrically isolates the patient from equipment connected to the domestic power system. This isolation may be accomplished, for example, by transformer coupling, acoustic coupling, or optical coupling.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that signal isolation systems be classified into class II because this device is neither life-sustaining nor life-supporting but is potentially hazardous to life or health even when properly used. If the device fails to properly isolate the subject, or to adequately transmit the electrical signal from the patient transducer or electrode to the monitoring equipment, electrical shock and misdiagnosis are significant potential hazards to the patient's health. The device is an interface between transducers and electrodes attached to the body and monitoring equipment connected to the demestic power system, and it is used in a clinical environment where excess electrical leakage current can be a serious hazard. Thus the electrical characteristics of this device, need to meet cerain requirements. Performance formance characteristics, including electrical isolation, of electrical function, and any limitations on the device's signal isolation capability should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls along would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Failure of the device to maintain electrical isolation can lead to the presence of excess electrical leakage current disturbing the normal electrophysiology of the heart and leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and

this can lead to iatrogenic complications. (b) Misdiagnosis: Inadequate frequency response and inaccuracy or instability of calibration of a device with which a signal isolation system is used can cause the device to generate inaccurate or insufficient diagnostic data. If inaccurate or insufficient diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the signal isolation system be classified into class II (performance standards). The Commissioner believes that a peformance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although signal isolation systems are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2600 as follows:

§ 870.2600 Signal isolation system.

(a) *Identification.* A signal isolation system is a device that electrically isolates the patient from equipment connected to the domestic power system. This isolation may be accomplished, for example, by transformer coupling, acoustic coupling, or optical coupling.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 p.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6156 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1460]

MEDICAL DEVICES

Classification of Line Isolation Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying line isolation monitors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of line isolation monitors:

1. Identification: A line isolation monitor is a device used to monitor the electrical leakage current from a power supply electrically isolated from the domestic power supply.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that line isolation monitors be classified into class II because the device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health even when properly used. If the device fails to monitor accurately leakage current or to keep the power supply isolated, excessive leakage current could be released into the clinical environment, creating a potential hazard of electrical shock to the patient. Performance characteristics including the accurate monitoring of leakage current and any limitations on the device's ability to maintain power supply isolation should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or electrical shock: Failure to accurately monitor the electrical leakage current or failure of the device to keep the power supply isolated can lead to excess leakage current, which can disturb the normal electrophysiology of the heart and lead to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician, during a catheterization or surgical procedure, and this can lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the line isolation monitor be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commis-

sioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although line isolation monitors are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2620 as follows:

§ 870.2620 Line isolation monitor.

(a) *Identification.* A line isolation monitor is a device used to monitor the electrical leakage current from a power supply electrically isolated from the domestic power supply.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal.

Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6157 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1461]

MEDICAL DEVICES

Classification of Portable Leakage Current Alarms

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying portable leakage current alarms into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fisher Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of portable leakage current alarms:

1. Identification: A portable leakage current alarm is a device used to measure the electrical leakage current between any two points of an electrical system and to sound an alarm if the current exceeds a certain threshold.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommends that portable leakage current alarms be classified into class II because the device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health even when properly used. If the device fails to detect excessive electrical leakage current, a potential hazard of electrical shock to the patient exists. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to measure electrical leakage current, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or electrical shock: An inaccuracy in the detection circuitry can lead to excessive electrical leakage current, which can disturb the normal electrophsiology of the heart and lead to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the portable leakage current alarm be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2640 as follows:

§ 870.2640 Portable leakage current alarm.

(a) *Identification.* A portable leakage current alarm is a device used to measure the electrical leakage current between any two points of an electrical system and to sound an alarm if the current exceeds a certain threshold.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written

comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE
Associate Commissioner for Regulatory Affairs

[FR Doc. 79-6158 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1462]

MEDICAL DEVICES

Classification of Oscillometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oscillometers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of oscillometers:

1. Identification: An oscillometer is a device used to measure physiological oscillations of any kind, e.g., changes in the volume of arteries.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priorty.

3. Summary of reasons for recommendation: The Panel recommends that oscillometers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through various types of transducers and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of a specific physiological parameter, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. If the device is inadequate for accurate and precise measurement of oscillations, the resulting misdiagnosis could have a significant negative effect on the patient's health. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards assoicated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero of calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the oscillometer be classifed into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although oscillometers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding a new § 870.2675 as follows:

§ 870.2675 Oscillometer.

(a) *Identification.* An oscillometer is a device used to measure physiological oscillations of any kind, e.g., changes in the volume of arteries.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20856, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6159 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1463]

MEDICAL DEVICES

Classification of Oximeters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oximeters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into Class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of oximeters:

1. Identification: An oximeter is a device used to transmit radiation at a known wavelength through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that oximeters be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood oxygen saturation, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through transducers or catheters and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g. electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood oxygen saturation, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Although the device releases into the body an acceptable energy level when functioning normally, unsafe energy levels may be released if the device malfunctions. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue damage and blood damage: Devices which emit energy into the body can emit such energy at levels which may damage tissue and blood if the device is not properly designed.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the oximeter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although oximeters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371 (a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in subpart C by adding new § 870.2700 as follows:

§ 870.2700 Oximeter.

(a) *Identification.* An oximeter is a device used to transmit radiation at a known wavelength through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.

(b) *Classification.* Class II (Performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6160 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1464]

MEDICAL DEVICES

Classification of Ear Oximeters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ear oximeters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ear oximeters:

1. Identification: An ear oximeter is an extravascular device used to transmit light at known wavelengths through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ear oximeters be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood oxygen saturation, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through transducers and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood oxygen saturation, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Although the device releases into the body an acceptable energy level when functioning normally, unsafe energy levels may be released if the device malfunctions. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue damage and blood damage: Devices which emit energy into the body can emit such energy at levels which damage tissue and blood if the device is not properly designed.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ear oximeter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although ear oximeters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, and Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2710 as follows:

§ 870.2710 Ear oximeter.

(a) *Identification.* An ear oximeter is an extravascular device used to transmit light at a known wavelength(s) through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be idenitifed with the Hearing Clerk docket number found brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: Februrary 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6161 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1465]

MEDICAL DEVICES

Classification of Impedance Phlebographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation clasifying impedance phlebographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of impedance phlebographs:

1. Identification: A impedance phlebograph is a device used to provide a visual display of the venous pulse or drainage by measuring electrical impedance changes in a region of the body.

2. Recommended clasification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that impedance phlebographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of venous pulse or drainage, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through electrodes and is used in a clinical enviroment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet cerain requirements. Although the device releases an acceptable energy level into the body when functioning normally, unsafe energy levels may be released if the device malfunctions. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of venous pulse or drainage, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendationon on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response of the device is improper, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the impedance phlebograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although impedance phlebographs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2750 as follows:

§ 870.2750 Impedance phlebograph.

(a) *Identification.* A impedance phlebograph is a device used to provide a visual display of the venous pulse or drainage by measuring electrical impedance changes in a region of the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6162 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1466]

MEDICAL DEVICES

Classification of Impedance Plethysmographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying impedance plethysmographs into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of impedance plethysmographs:

1. Identification: An impedance plethysmograph is a device used to estimate blood flow by measuring electrical impedance changes in a region of the body.

2. Recommended classification: Class II (performance standard). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that impedance plethysmographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood flow, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Although the device releases an acceptable energy level into the body when functioning normally, unsafe energy levels may be released if the device malfunctions. Performance characteristics including accuracy, reproducibility, and any limitations on the device's measurement of blood flow, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if frequency response of the device is improper, the device can generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendations of the Panels and is proposing that the impedance plethysmograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A preformance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because the measurement of blood flow is an indicator of cardiovalcular function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although impedance plethysmographs are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2770 as follows:

§ 870.2770 Impedance plethysmograph.

(a) *Identification.* An impedance plethysmograph is a device used to estimate blood flow by measuring electrical impedance changes in a region of the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 71-6163 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1457]

MEDICAL DEVICES

Classification of Hydraulic, Pneumatic, and Photoelectric Plethysmographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hydraulic, pneumatic, and

photoelectric plethysmographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of hydraulic, pneumatic, and photoelectric plethysmographs:

1. Identification: A hydraulic, pneumatic, and photoelectric plethysmograph is a device used to estimate blood flow in a region of the body using hydraulic, pneumatic, or photoelectric measurement techniques.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hydraulic, pneumatic, and photoelectric plethysmograph be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood flow, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through electrical sensors and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics including accuracy, reproducibility, and any limitations on the device's measurement of blood flow, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response of the device is improper, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue ischemia: Excessive or prolonged pressure in the cuff of a plethysomograph, which uses vessel occlusion techniques for estimation of blood flow, can cause tissue ischemia (deficiency of blood supply to a portion of the body).

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the hydraulic, pneumatic, and photoelectric plethysmograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although hydraulic, pneumatic, and photoelectric plethysmographs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2780 as follows:

§ 870.2780 Hydraulic, pneumatic, and photoelectric plethysmographs.

(a) *Identification.* A hydraulic, pneumatic, or photoelectric plethysmograph is a device used to estimate blood flow in a region of the body using hydraulic, pneumatic, or photoelectric measurement techniques.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6164 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1468]

MEDICAL DEVICES

Classification of Medical Magnetic Tape Recorders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying medical magnetic tape recorders into class II (performance

standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of medical magnetic tape recorders:

1. Identification: A medical magnetic tape recorder is device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that medical magnetic tape recorders be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the recording or playback of signals does not allow accurate and precise determination of a specific physiological function, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through transducers, catheters, or electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain characteristics, including accuracy, reproducibility, and any limitations on the device's recording of electrical signals, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response of the device is improper, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the medical magnetic tape recorder be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although medical magnetic tape recorders are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2800 as follows:

§ 870.2800 Medical magnetic tape recorder.

(a) *Identification.* A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6165 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1469]

Medical Devices

Classification of Paper Chart Recorders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying paper chart recorders into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Ophthalmic Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more perform-

ance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4.65. 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the Ophthalmic Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of paper chart recorders:

1. Identification: A paper chart recorder is a device used to print on paper, and create a permanent record of, the signal from, for example, a physiological signal amplifier, signal conditioner, or computer.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that paper chart recorders be classified into class II becasue this electrically powered device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. If the charted display provided by the device is inadequate for accurate and precise determination of a specific physiological parameter, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through transducers, catheters, or electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's recording of electrical signals, should be maintained at a generally accepted satisfactory level and should be made know to the user through special labeling. The device is used with other devices in a system that may be hazardous if not properly assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response of the device is improper, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the paper chart recorder be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because paper chart recorders are used most frequently with cardiovascular devices, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although paper chart recorders are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2810 as follows:

§ 870.2810 Paper chart recorder.

(a) *Identification.* A paper chart recorder is a device used to print on paper, and create a permanent record of, the signal from, for example, a physiological amplifier, signal conditioner, or computer.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6186 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1470]

MEDICAL DEVICES

Classification of Apex Cardiographic Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying apex cardiographic transducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the

safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of apex cardiographic transducers:

1. Identification: An apex cardiographic transducer is a device used to detect motion of the heart (acceleration, velocity, or displacement) by changes in the mechanical or electrical properties of the device.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that apex cardiographic transducers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the signal produced by the transducer is inadequate for accurate and precise measurement of heart movement, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through the skin and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to detect heart movement, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the apex cardiographic transducer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although apex cardiographic transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2840 as follows:

§ 870.2840 Apex cardiographic transducer.

(a) *Identification.* An apex cardiographic transducer is a device used to detect motion of the heart (acceleration, velocity, or displacement) by changes in the mechanical or electrical properties of the device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979,

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6167 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1471]

MEDICAL DEVICES

Classification of Extravascular Blood Pressure Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying extravascular blood pressure transducers into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effec-

tive 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of extravascular blood pressure transducers:

1. Identification: An extravascular blood pressure transducer is a device used to measure blood pressure by changes in mechanical or electrical properties of the device. The proximal end of the transducer is connected to a pressure monitor that produces an analog or digital electrical signal related to changes in the electrical or mechanical changes produced in the transducer.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that extravascular blood pressure transducers be classified into class II because this electrically operated device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body by in-line contact with the blood in a catheter system and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to sense blood pressure should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on thier personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or claibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendations of the Panels and is proposing that the extravascular blood pressure transducer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although extravascular blood pressure transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2850 as follows:

§ 870.2850 Extravascular blood pressure transducer.

(a) *Identification.* An extravascular blood pressure tranducer is a device used to measure blood pressure by changes in the mechanical or electrical properties of the device. The proximal end of the transducer is connected to a pressure monitor that produces an analog or digital electrical signal related to changes in the electrical or mechanical changes produced in the transducer.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6168 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1472]

MEDICAL DEVICES

Classification of Heart Sound Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying heart sound transducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of heart sound transducers:

1. Identification: A heart sound transducer is an external transducer which exhibits a change in mechanical or electrical properties in relation to sounds produced by the heart. This device may be used in conjunction with a phonocardiograph to record heart sounds.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the heart sound transducer be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise detection of heart sounds, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through the skin and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics including accuracy, reproducibility, and any limitations on the device's ability to detect heart sounds should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of date on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the heart sound transducer be classified into class II (performance standards). The Commissioners believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although heart sound transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2860 as follows:

§ 870.2860 Heart sound transducer.

(a) *Identification.* A heart sound transducer is an external transducer that exhibits a change in mechanical or electrical properties in relation to sounds produced by the heart. This device may be used in conjunction with a phonocardiograph to record heart sounds.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submits single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6169 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1473]

MEDICAL DEVICES

Classification of Catheter Tip Pressure Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter tip pressure transducers into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of catheter tip pressure transducers:

1. Identification: A catheter tip pressure transducer is a device incorporated into the distal end of a catheter. When placed in the bloodstream, its mechanical or electrical properties change in realtaion to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

2. Recommended clasification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that the catheter tip pressure transducer be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is placed in direct contact with the bloodstream and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to measure blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophsiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating of fatal thromboemboli. (d) Embolism: Pieces of the transducer or catheter which break or flake off may form potentially debilitating or fatal emboli. (e) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the catheter tip pressure transducer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovalcular devices. Although catheter tip pressure transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the R under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2870 as follows:

§ 870.2870 Catheter tip pressure transducer.

(a) *Identification.* A catheter tip pressure transducer is a device incorporated into the distal end of a catheter. When placed in the bloodstream, its mechanical or electrical properties change in relation to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fisher Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6170 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1474]

MEDICAL DEVICES

Classification of Ultrasonic Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultrasonic transducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of

the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ultrasonic transducers:

1. Identification: An ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ultrasonic transducers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise cardiac imaging, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through the skin and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, any limitations on the device's ability to provide cardiac imaging, and the level of ultrasonic energy injected into the body, should be maintained at generally accepted satisfactory levels and should be made known to users through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue and blood damage: If the device is not properly designed, ultrasonic energy may be released into the body at levels that may damage tissue and blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ultrasonic transducer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although ultrasonic transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2880 as follows:

§ 870.2880 Ultrasonic transducer.

(a) *Identification.* A ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6171 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1475]

MEDICAL DEVICES

Classification of Vessel Occlusion Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vessel occlusion transducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDRAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of vessel occlusion transducers:

1. Identification: A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the vessel occlusion transducer be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the response of the transducer to the sounds is inadequate for accurate and precise detection of a partially occluded vessel, the resulting misdiagnosis could have a significant negative effect on the patient's health. The device is in direct contact with the surface of the body and may be used in a clinical environment where the transmission of electrical leakage current to the body presents a serious health hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to detect vessel occlusion, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. In the case of ultrasonic devices of this category, malfunction of the device may result in exposure of the body to an unsafe amount of ultrasonic energy. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue and blood damage: If the device is not properly designed, ultrasonic energy may be released into the body at levels that may damage tissue and blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vessel occlusion transducer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although vessel occlusion transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2890 as follows:

§ 870.2890 Vessel occlusion transducer.

(a) *Identification.* A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6172 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1476]

MEDICAL DEVICES

Classification of Patient Transducer and Electrode Cables (Including Connector)

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying patient transducer and electrode cables (including connector) into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effec-

tive 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of patient transducer and electrode cables (including connector):

1. Identification: A patient transducer and electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that patient transducers and electrode cables (including connectors) be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through electrodes or transducers and is used in a clinical environment where transmission of excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that each type of cable connector should be standardized uniquely so that, for example, an electrocardiograph cable cannot be connected to a pressure transducer cable connector where the transducer excitation signal may cause the heart to fibrillate. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Failure to transmit signal or intermittent transmission or electrical leakage: Poor mechanical design of the conductor and insulating material, and the inability of the device to withstand sterilization cycles may lead to signal transmission failures or electrical leakage.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the patient transducer and electrode cable (including connector) be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although patient transducer and electrode cables (including connector) are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2900 as follows:

§ 870.2900 Patient transducer and electrode cable (including connector).

(a) *Identification.* A patient transducer and electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6173 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1477]

MEDICAL DEVICES

Classification of Radiofrequency Physiological Signal Transmitters and Receivers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radiofrequency physiological signal transmitters and receivers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of radiofrequency physiological signal transmitters and receivers:

1. Identification: A radiofrequency physiological signal transmitter and receiver is a device used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station. The received signal is reconditioned by the device into its original format so that it can be displayed.

2. Recommended clasification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that radiofrequency physiological signal transmitters and receivers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through transducers or electrodes and is used in a clinical enviroment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the data conditioning or transmission is inadequate for accurate and precise measurement of a given physiological signal, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics including effective data transmission and any limitations on the device's performance characteristics should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: Inadequate frequency response of the transmitter-receiver system can lead to loss of data in transmission or to the generation of inaccurate diagnostic data. Inaccuracy or instability of zero or calibration can also lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Interference with or from other medical devices: Electromagnetic interference to or by the radiofrequency signal can lead to a malfunction of this device or other devices in the immediate vicinity. (d) Tissue damage: Excessive radiofrequency energy can possibly cause tissue damage.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the radiofrequency physiological signal transmitter and receiver be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although radiofrequency physiological signal transmitters and receivers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices becasue monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2910 as follows:

§ 870.2190 Radiofrequency physiological signal transmitters and receivers.

(a) *Identification.* A radiofrequency physiological signal transmitter and receiver is a device used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station. The received signal is reconditioned by the device into its original format so that it can be displayed.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6174 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1478]

MEDICAL DEVICES

Classification of Telephone Electrocardiograph Transmitters and Receivers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying telephone electrocardiograph transmitters and receivers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs

proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of telephone electrocardiograph transmitters and receivers:

1. Identification: A telephone electrocardiograph transmitter and receiver is a device used to condition an ECG signal so that it can be transmitted via a telephone line to another location. This device also includes a receiver that reconditions the received signal into its original format so that it can be displayed. The device includes devices used to transmit and receive pacemaker signals.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that telephone electrocardiograph transmitters and receivers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through ECG electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the data conditioning or transmission is inadequate for accurate and precise measurement of the ECG or heart rate, the resulting misdiagnosis could have a significant negative effect upon the patient's health. Performance characteristics, including effective data transmission and any limitations on the device's performance characteristics, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: Inadequate frequency response of the transmitter-receiver system can lead to loss of data in transmission or to the generation of inaccurate diagnostic data. Inaccuracy or instability of zero or calibration can also lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the telephone electrocardiograph transmitter and receiver be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although telephone electrocardiograph transmitters and receivers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2920 as follows:

§ 870.2920 Telephone electrocardiograph transmitters and receivers.

(a) *Identification.* A telephone electrocardiograph transmitter and receiver is a device used to condition an ECG signal so that it can be transmitted via a telephone line to another location. This device also includes a receiver that reconditions the received signal into its original format so that it can be displayed. The device includes devices used to transmit and receive pacemaker signals.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regardng this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6175 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1479]

MEDICAL DEVICES

Classification of Vascular Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vascular clips into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These ac-

tions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vascular clips:

1. Identification: A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that vascular clips be classified into class II because this implanted device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's tensile and grasp strength, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. Although the device is an implant, the Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel found further support for their recommendation in the medical literature. This literature includes a review of over 40 types of malleable, screw, and spring clips (Ref. 1) in which 3 types of hazards associated with the device are cited. The main hazard noted is tissue damage due to a severing of the vessel (Ref. 1) or the application of excess pressure (Ref. 2). Both types of tissue damage can result from poor mechanical design. Slippage is another hazard associated with poor mechanical design and is especially prominent with clips that are not grooved (Refs. 1 through 5). A third hazard is ineffective occulsion of the vessel when the pressure originally applied is reduced because of material creep (stress relief in a material due to plastic deformation occurring over a long period of time). This hazard is associated most frequently with plastic clips. Vascular clips serve the same function as suture or hemostatic clamps and apparently are most valuable when used in relatively inaccessible areas (Ref. 3).

5. Risks to health: (a) Tissue damage: Damage to the vessel may result because of poor mechanical design of the device or tissue incompatibility of the materials used in the device. (b) Bleeding from loss of occlusion: The occlusion caused by the device may become ineffective due to material creep. (c) Bleeding due to clip slippage: Slippage may result from poor mechanical design of the device.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vascular clip be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that, although the device is an implant, there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Fox, J. L., "Vascular Clips for the Microsurgical Treatment of Stroke," *Stroke*, 7(5):489-500, 1976.

2. Sugita, K. et al. "Comparative Study of the Pressure of Various Aneurysm Clips," *Journal of Neurosurgery*, 44(6):723-727, 1976.

3. Parris, E. B., "The Use of Hemostatic Clips in General Surgery," *American Journal of Proctology*, 23(6):484-488, 1972.

4. Samuels, P. B. and J. J. Cincotti, "The Use of Hemostatic Clips in Vascular Surgery," *Journal of Cardiovascuar Surgery* (Torino), 9(2):150-153, 1968.

5. Drake, C. G. and T. J. Allcock, "Postoperative Angiography and the 'Slipped' Clip," *Journal of Neurosurgery*, 39:683-689, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend part 870 by adding new Subpart D and new § 870.3250 as follows:

Subpart D—Cardiovascular Prosthetic Devices

§ 870.3250 Vascular clip.

(a) *Identification.* A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6176 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1480]

MEDICAL DEVICES

Classification of Vena Cava Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vena cava clips into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979.

The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vena cava clips:

1. Identification: A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the vena cava clip be classified into class II because this implanted device is neither life-supporting nor life-sustaining, but is potentialy hazardous to life or health even when properly used. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's tensile and grasp strength, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. Although the device is an implant, the Panel believes that a performance standards will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel found further support for their recommendation in the medical literature. This review included a comparison of the four commonly used methods of vena cava interruption: ligation (complete occlusion), plication (narrowing by suture techniques), intracaval filtering, the clipping. The vena cava clip has no blood-material interface. Because it is only partially occlusive it causes less hemodynamic alteration than does ligation (Refs. 2, 4 through 6, 8 through 11, and 13). Tissue damage, however, may result from poor mechanical design. clips with teeth on both jaws, for example, are more likely to snag or tear the vena cava or surrounding structures (Ref. 7). Also, large pressures produced in the cava during coughing or sneezing tend to dislodge a clip that does not permit secure closure (Ref. 7). Finally, ineffective occlusion can result as the original pressure applied by a plastic clip is reduced by material creep (stress relief due to plastic deformation of the material over a long time period). While the percentage of embolism recurrence varies from report to report, it is generally agreed that these clips are at least as safe and effective as ligation, plication, or filtering (Refs. 1, 2, 6, 8, 9, 11, and 14).

5. Risks to health: (a) Tissue damage: Damage to the vessel may occur because of poor mechanical design of the device or tissue incompatibility of the materials used in the device. (b) Recurrent thromboemboli: Relaxation of the device due to material creep can lead to recurrent pulmonary thromboemboli, which can be debilitating or fatal.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vena cava clip be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that, although the device is an implant, there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Taber, R. I., et al., "Prevention of Pulmonary Emboli with a Vena Caval Clip," *Journal of the American Medical Association*, 195(11):889-894, 1966.

2. Moretz, W. H., et al., "Partial Occlusion of the Inferior Vena Cava with a Smooth Teflon Clip: Analysis of Long-Term Results," *Surgery*, 71(5):710-719, 1972.

3. Mullick, S. C. and H. B. Wheeler, "Recurrent Pulmonary Emboli After Inferior Vena Caval Clipping," *American Journal of Surgery*, 119:746-748, 1970.

4. Neeley, R. and J. R. Allenberg, "Acute Cardiovascular Effects of Vena Cava Interruption: Ligation Versus Clip Compartmentation with Cardiac Output and Flow Measurements," *Surgery*, 66(4):762-764, 1969.

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9. Miles, R. M., "Prevention of Pulmonary Embolism by the Use of a Plastic Vena Caval Clip," *Annals of Surgery, 163(2):192-198, 1966.*

10. Silver, D. and D. C. Sabiston, "The Role of Vena Caval Interruption in the Management of Pulmonary Embolism," *Surgery*, 77(1):1-10, 1975.

11. Poliak, E. W., F. C. Sparks, and W. F. Barker, "Inferior Vena Cava Interruption: Indications and Results with Caval Ligation, Clips and Intracaval Devices in 110 Cases," *Journal of Cardiovascular Surgery*, 15:629-635, 1974.

12. Gardner, A. M. N., "Partial Inferior Vena Caval Occlusion Clip," *Proceedings Royal Society Medicine*, 67(1), 1974.

13. Miyauchi, Y. and B. C. Paton, "Teflon Serrated Clips for Prevention of Pulmonary

Embolis," *American Surgery*, 32(9):609–614, 1966.

14. Hendricks, G. L. and W. T. Barnes, "Experiences with the Clip: 100 Cases," *American Surgeon*, 37(9):558–562, 1971.

Therefore under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3260 as follows:

§ 870.3260 Vena cava clip.

(a) *Identification.* A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6177 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1481]

MEDICAL DEVICES

Classification of Peripheral Arterial Embolization Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying peripheral arterial embolization devices into class III (premarket approval). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTRAY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of peripheral arterial embolization devices:

1. Identification: A peripheral arterial embolization device is an intravascular implant used to occlude certain arteries to halt blood flow in arteries supplying certain types of abdominal tumors (e.g., nephroma, hepatoma) or to control internal hemorrhage.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the peripheral arterial embolization device be classified into class III because the Panel believes that premarket approval is necessary to assure the safety and effectiveness of this device and because the device is an implant that presents a potential unreasonable risk of illness or injury. If the device fails to halt blood flow when used to control internal hemorrhaging, the resulting continued bleeding can be debilitating or fatal. Migration of the device can lead to halting the blood supply to healthy tissue. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is insufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli. (b) Inadvertent embolization and infarction: If the design of the device makes proper positioning difficult, erroneous placement or migration could occur and cause a potentially debilitating infarction of healthy tissue. (c) Vessel perforation: If the surface of the device is rough or sharp, or if the device causes excessive inflammation, vessel perforation may result. (d) Progressive granulomatous inflammation: The materials used in the device or the mechanical design of the device can lead to progressive granulomatous inflammation (localized tissue response characterized by a tumor-like mass). (e) Infection: By design, the device could have obscured areas of contamination, making sterilization difficult and possibly leading to infections.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the peripheral arterial embolization device be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use in treatment of tumors and control of internal hemorrhage, which is of substantial importance in preventing impairment of human health. The device is intended to be implanted into the human body. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because the device may inadvertently halt blood flow to a normal, healthy section of tissue. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a per-

formance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3300 as follows:

§ 870.3300 Peripheral arterial embolization device.

(a) *Identification.* A peripheral arterial embolization device is an intravascular implant used to occlude certain arteries to halt blood flow in arteries supplying certain types of abdominal tumors (e.g., nephroma, hepatoma) or to control internal hemorrhage.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6178 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1482]

MEDICAL DEVICES

Classification of Cardiovascular Intravascular Filters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiovascular intravascular filters into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiovascular intravascular filters:

1. Identification: An intravascular filter is an implant that is placed in the inferior vena cava for the purpose of preventing pulmonary thromboemboli (blood clots generated in the lower limbs and broken loose into the bloodstream) from flowing into the right side of the heart and the pulmonary circulation.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiovascular intravascular filters be classified into class III because the device is an implant used for a life-sustaining purpose. The materials used in the device and its design should minimize thromboembolic complications and the tendency to perforate the vena cava. The device should allow as much venous blood to return to the right heart as possible. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance. The Panel believes that premarket approval is necessary to assure the safety and effectiveness of this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, their personal knowledge of, and experience with, the device, and the fact that the device is an implant used for a life-sustaining purpose.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Vena cava perforation: Improper design of the mechanical fixation of the device to the vein can cause perforation of the vena cava. (c) Decreased blood flow to the right heart: The hemodynamic design of the device is associated with the possibility of a serious reduction in the amount of blood return to the right heart.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiovascular intravascular filters be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (prevention of pulmonary thromboemboli) in supporting or sustaining human life. The device is intended to be implanted into the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3375 as follows:

§ 870.3375 Cardiovascular intravascular filter.

(a) *Identification.* An intravascular filter is an implant that is placed in

the inferior vena cava for the purpose of preventing pulmonary thromboemboli (blood clots generated in the lower limbs and broken loose into the blood stream) from flowing into the right side of the heart and the pulmonary circulation.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, RM. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6179 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1483]

MEDICAL DEVICES

Classification of Vascular Graft Prostheses of Less Than 6 Millimeters in Diameter

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vascular graft prostheses of less than 6 millimeters (mm) diameter into class III (premarket approval). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK—450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of vascular graft prostheses of less than 6 mm diameter:

1. Identification: A vascular graft prosthesis of less than 6 millimeters (mm) diameter is a device used to replace sections of small arteries. These grafts are commonly constructed of woven or knitted materials such as Dacron and Teflon.

2. Recommended classification: Class III (premarket approval). The Panels recommend that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that vascular graft prostheses of less than 6 mm in diameter be classified into class III because the device is implanted and is life-sustaining. The Panels believe that artificial grafts of less thn 6 mm diameter have not performed as well as the alternatives of endarterectomy and autogenous vein grafting. The reasons for this poorer performance are not known. Material or mechanical properties can have a substantial effect upon the behavior of the device, but until data exist showing safety and efficacy related to physical, chemical, and material properties, clinical trials are necessary to establish the safety and effectiveness of the device. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels do not believe that sufficient scientific and medical data exist to establish standards to assure the safety and efficacy of this implanted device.

4. Summary of data on which the recommendation is based: The members of the Panels based their recommendtions on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panels found further support for their recommendations in the medical literature. The following complications were cited in the literature reviewed by the Panels: thromboembolic complications (Refs. 1 through 6); failure to heal properly, including insufficient or excessive tissue ingrowth resulting in failure to incorporate the graft in the neointima (Refs. 2, 4, and 6) and stenosis (Refs. 7, 8); material or mechanical failures (Refs. 4, 5, 9, and 10); hemolysis (Ref. 14); sarcoma (Ref. 15); late infection (Ref. 16); and aneurysms and dilation of the prosthesis or "false aneurysm" (Refs. 2, 4, 9, and 19). Material and mechanical failures include kinking (Refs. 4 and 5) and dilation (Refs. 2, 4, 9, and 19). Because of loss of tensile strength, use of nylon materials was abandoned (Refs. 5 and 10). Blood compatibility of the materials has always been a problem, because no truly blood-compatible artificial material has been discovered. Thrombogenicity of the materials should be reduced to a minimum. However, there is no present agreement on the most effective means to achieve this. For example, Guidoin (Ref. 20) cited conflicting reports on the thrombogenicity of Dacron used in vascular graft prosthesis. Szilagyi et al. (Ref. 2) reported late patency of 15 percent for artificial grafts in the femoralpopliteal position, while endarterectomy and autogenous vein grafts had late patencies of 90 percent and 80 percent, respectively. Some more recent experimental projects have shown promise for increased safety and efficacy in small artery and venous applications. These include the use of electrically conductive materials (Ref. 7), heparinization (Ref. 21), biological preparations of artificial grafts (Ref. 1), and expanded polytetrafluoroethylene (Refs. 17 and 18). Despite this progress, premarket approval is warranted for this device because clinical trials are still needed to establish safety and efficacy.

5. Risks to health: (a) Clot formation: Material incompatibility with the blood can lead to clot formation. (b) Ripping of the graft: An improper design of the graft stitch can cause ripping of the graft when punctured with a surgical needle. (c) Dilatation: Dilatation can result from insufficient physical strength of the material or from improper design of the weave or knit pattern of the graft. (d) Blood seepage or leakage: Inadequate preclotting of the graft can cause seepage or leakage of blood through the graft wall.

The Commissioner agrees with the Panel's recommendation and is proposing that the vascular graft prosthesis of less than 6 mm diameter be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (artery replacement) in supporting or sustaining human life. The device is intended to be implanted into the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance. Because it is used solely in cardiovascular surgery, this device will be listed in the Code of Federal Regulations under cardiovascular devices.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hansen, O. K., O. Kraft, C. Mouritzen, "Biologic and Semibiologic Vascular Grafts," *Surgery, Gynecology, and Obstetrics*, 138:940-944, 1974.

2. Szilagyi, D. E., R. F. Smith, J. P. Elliot, and H. M. Allen, "Long-Term Behavior of a Dacron Arterial Substitute," *Annals of Surgery*, 162(3):453-477, 1965.

3. Berger, S. and E. W. Salzman, "Thromboembolic Complications of Prosthetic Devices," *Progress in Hemostasis and Thrombosis*, 2:273-309, 1974.

4. Hallin, R. W., "Complications with the Mandril-Grown (Sparks) Dacron Arterial Graft," *American Surgeon*, 41(9):550-554, 1975.

5. Szilagyi, D. E., J. R. Pfeifer, and F. J. DeRusso, "Long-Term Evaluation of Plastic Arterial Substitutes: An Experimental Study," *Surgery*, 55(1):165-183, 1964.

6. Sauvage, L. R., "The Future of Porous-Fabric Arterial Prostheses," *Annals of Thoracic Surgery*, 19:333-335, 1975.

7. Miller, B. G., K. A. Dyer, B. C. Taylor, J. I. Wright, and W. V. Sharp, "Electrical Conductivity: Effect on Intravascular Performance of Foams, Velour, Flock and Fabric," *Transactions of the American Society for Artificial Internal Organs*, 20:91-100, 1974.

8. Weinstein, G., A. J. Franzone, S. H. Stertzer, and W. Walsh, "Subvalvular Stenosis of Aortic Prostheses," *Journal of Thoracic and Cardiovascular Surgery*, 68:17-20, 1974

9. Ottinger, L. W., R. C. Darling, R. S. Wuithlin, and R. R. Linton, "Failure of Ultralightweight Knitted Dacron Grafts in Arterial Reconstruction," *Archives of Surgery*, 111:146-149, 1976.

10. Lindenauer, S. M., T. R. Weber, T. A. Miller, S. R. Ramsbaugh, C. A. Salles, S. P. Kahn, and R. W. Wojtalik, "The Use of Velour as a Vascular Prosthesis," *Biomedical Engineering*, 11(9):301-306, 1976.

11. Deterling, R. A., "Editorial: Failure of Dacron Arterial Prostheses," *Archives of Surgery*, 108:113, 1974.

12. Cooke, P. A., P. A. Nobis, and R. J. Stoney, "Dacron Aortic Graft Failure," *Archives of Surgery*, 108:101-103, 1974.

13. Hayward, R. H. and F. L. Korompai, "Degeneration of Knitted Dacron Grafts," *Surgery*, 79(5):581-583, 1976.

14. Singh, A., E. A. Letsky, and J. Stark, "Hemolysis Following Correction of Double-Outlet Right Ventricle," *Journal of Thoracic and Cardiovascular Surgery*, 71(2):226-229, 1976.

15. O'Connell, T. X., H. J. Fee, and A. Golding, "Sarcoma Associated with Dacron Prosthetic Material," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):94-96, 1976.

16. Thompson, J., T. Dirksen, M. Nube, and A. G. Brom, "Prosthesis Endocarditis," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):28-32, 1976.

17. Florian, A., L. H. Cohn, G. J. Dammin, and J. J. Collins, "Small Vessel Replacement with Gore-tex (Expanded Polytetrafluoroethylene)," *Archives of Surgery*, 111:267-270, 1976.

18. Campbell, C. D., D. Goldfarba, D. D. Detton, R. Roe, K. Goldsmitn, and E. B Diethrich, "Expanded Polytetrafluoroethylene as a Small Artery Substitute," *Transactions of the American Society for Artifical Internal Organs*, 20:86-90, 1974.

19. Read, R. C., "Uninfected Anastomotic False Aneurysms Following Arterial Reconstructuring with Prosthetic Grafts," *Journal of Cardiovascular Surgery*, 16:558-561, 1975.

20. Guidoin, R. G., J. A. Awad, C. Gosselin, C. Rouleau, and G. H. Haggis, "Preclotting and Thrombosis of a Dacron Prosthesis: A Scanning Electron Microscope Study," *Biomaterials, Medical Devices, and Artificial Organs*, 3(3):365-382, 1975.

21. Leininger, R. I., J. P. Crowley, R. D. Falb, and G. A. Grode, "Three Years' Experience in vivo and in vitro with Surfaces and Devices Treated by the Heparin Complex Method," *Transactions of the American Society for Artificial Internal Organs*, 18:312-315, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3450 as follows:

§ 870.3450 Vascular graft prosthesis of less than 6 millimeters in diameter.

(a) *Identification.* A vascular graft prosthesis of less than 6 millimeters (mm) diameter is a device used to replace sections of small arteries. These grafts are commonly constructed of woven or knitted materials such as Dacron and Teflon.

(b) *Classification.* Class III (permarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6180 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1484]

MEDICAL DEVICES

Classification of Vascular Graft Prostheses of 6 Millimeters and Greater Diameter

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifyng vascular graft prostheses of 6 millimeters (mm) and greater diameter into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of vascular graft prostheses of 6 mm and greater diameter:

1. Identification: A vascular graft prosthesis of 6 millimeters (mm) and greater diameter is a device used to replace sections of arteries. These grafts are commonly constructed of woven or knitted materials such as Dacron and Teflon.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Although the device is implanted and life sustaining, the Panels recommend that vascular graft prostheses of 6 mm and greater diameter be classified into class II. Vascular grafts of 6 mm and greater in diameter perform as well as the alternatives of endarterctomy or autogenous vein grafts. Because of the tissue and blood interfaces involved in the use of these devices, the materials need to be controlled by standards. In addition, the device has characteristics, such as porosity and tensile strength, that should be maintained at a generally accepted satisfactory level. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of this implanted device and, moreover, that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panels found further support for their recommendations in the medical literature. In the literature reviewed by the Panels, the following complications were cited: thromboembolic complications (Refs. 1 through 6); failure to heal properly, including insufficient or excessive tissue ingrowth, resulting in failure to incorporate graft in neointima (Refs. 2, 4, and 6) and stenosis (Refs. 7 and 8); material or mechanical failures (Refs. 4, 5, and 9 through 13); hemolysis (Ref. 14); sarcoma (Ref. 15); late infection (Ref. 16); aneurysms and dilation of the prostheses or "false aneurysm" (Refs. 2, 4, 9, and 19). Material and mechanical failures include kinking (Refs. 4 and 5) and dilation (Refs. 2, 4, 9, and 19). Loss of tensile strength occurred with nylon materials and caused them to be abandoned (Refs. 5 and 10). Blood compatibility of the materials has always been a problem, because no truly blood-compatible artificial material has been discovered. Yet, thrombogenicity of the materials used should be reduced to a minimum. However, there is no present agreement on the most effective means to achieve this. For example, Guidoin (Ref. 20) cited conflicting reports on the thrombogenicity of Dacron used in vascular graft prostheses. for materials now used, it appears that artificial grafts of 6 mm and greater in diameter compare favorably with alternative forms of vascular replacement. In 1965, Szilagyi (Ref. 2) reported late patency of 85 percent for artificial grafts in the aortoiliac position, while endarterectomy and autogenous vein grafts had late patencies of 90 percent and 80 percent, respectively.

5. Risks to health: (a) Clot formation: Material incompatibility with the blood can lead to clot formation. (b) Ripping of the graft: An improper design of the graft stitch can cause ripping of the graft when punctured with a surgical needle. (c) Dilatation: dilatation can result from insufficient physical strength of the material or from improper design of the weave or knit pattern of the graft. (d) Blood seepage or leakage: Inadequate preclotting of the graft can cause seepage or leakage of blood through the graft wall.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the vascular graft prosthesis of 6 mm and greater diameter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that, although the device is an implant, there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because the device is used solely in cardiovascular surgery, this device will be listed in the Code of Federal Regulations under cardiovascular devices.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hansen, O. K., O. Kraft, and C. Mouritzen, "Biologic and Semibiologic Vascular Grafts," *Surgery, Gynecology, and Obstetrics*, 138:940-944, 1974.

2. Szilagyi, D. E., R. F. Smith, J. P. Elliot, and H. M. Allen, "Long-Term Behavior of a Dacron Arterial Substitute," *Annals of Surgery*, 162(3):453-477, 1965.

3. Berger, S. and E. W. Salzman, "Thromboembolic Complications of Prosthetic Devices," *Progress in Hemostasis and Thrombosis*, 2:273-309, 1974.

4. Hallin, R. W., "Complications with the Mandril-Grown (Sparks) Dacron Arterial Graft," *American Surgeon*, 41(9):550-554, 1975.

5. Szilagyi, D. E., J. R. Pfeifer, and F. J. DeRusso, "Long-Term Evaluation of Plastic Arterial Substitutes: An experimental Study," *Surgery*, 55(1):165-183, 1964.

6. Sauvage, L. R., "The Future of Porous-Fabric Arterial Prostheses," *Annals of Thoracic Surgery*, 19:333-335, 1975.

7. Miller, B. G., K. A. Dyer, B. C. Taylor, J. I. Wright, and W. V. Sharp, "Electrical Conductivity: Effect on Intravascular Performance of Foams, Velour, Flock and Fabric," *Transactions of the American Society for Artificial Internal Organs*, 20:91-100, 1974.

8. Weinstein, G., A. J. Franzone, S. H. Stertzer, and E. Walish, "Subvalvular Stenosis of Aortic Prostheses," *Journal of Thoracic and Cardiovascular Surgery*, 68:17-20, 1974.

9. Ottinger, L. W., R. C. Darling, R. S. Wuithlin, and R. R. Linton, "Failure of Ultralightweight Knitted Dacron Grafts in Arterial Reconstruction," *Archives of Surgery*, 111:146-149, 1976.

10. Lindenauer, S. M., T. R. Weber, T. A. Miller, S. R. Ramsbaugh, C. A. Salles, S. P. Kahn, R. S. Wojtalik, "The Use of Velour as a Vascular Prosthesis," *Biomedical Engineering*, 11(9):301-306, 1976.

11. Deterling, R. A., "Editorial: Failure of Dacron Arterial Prostheses," *Archives of Surgery*, 108:113, 1974.

12. Cooke, P. A., P. A. Nobis, and R. J. Stoney, "Dacron Aortic Graft Failure," *Archives of Surgery*, 108:101-103, 1974.

13. Hayward, R. H. and F. L. Korompai, "Degeneration of Knitted Dacron Grafts," *Surgery*, 79(5):581-583, 1976.

14. Singh, A., E. A. Letsky, and J. Stark, "Hemolysis Following Correction of Double-Outlet Right Ventricle," *Journal of Thoracic and Cardiovascular Surgery*, 71(2):226-229, 1976.

15. O'Connell, T. X., H. J. Fee, and J. Golding, "Sarcoma Associated with Dacron Prosthetic Material," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):94-96, 1976.

16. Thompson, J., T. Kirksen, M. Nube, and A. G. Brom, "Prosthesis Endocarditis," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):28-32, 1976.

17. Florian, A., L. H. Cohn, G. J. Dammin, and J. J. Collins, "Small Vessel Replacement with Gore-tex (Expanded Polytetrafluoroethylene)," *Archives of Surgery*, 111:267-270, 1976.

18. Campbell, C. D., D. Goldfarb, R. Roe, K. Goldsmith, and E. B. Diethrich, "Expanded Polytetrafluoro-ethylene as a Small Artery Substitute," *Transactions of the American Society for Artificial Internal Organs*, 20:86-90, 1974.

19. Read, R. C., "Uninfected Anastomotic False Aneurysms Following Arterial Reconstruction with Prosthetic Grafts," *Journal of Cardiovascular Surgery*, 16:558-561, 1975.

20. Guidoin, R. G., J. A. Awad, C. Gosselin, C. Rouleau, and G. H. Haggis, "Preclotting and Thrombosis of a Dacron Prosthesis: A Scanning Electron Microscope Study," *Biomaterials, Medical Devices, and Artificial Organs*, 3(3):365-382, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3460 as follows:

§ 870.3460 Vascular graft prostheses of 6 millimeters and greater diameter.

(a) *Identification.* A vascular graft prosthesis of 6 millimeters (mm) and greater diameter is a device used to replace sections of arteries. These grafts are commonly constructed of woven or knitted materials such as Dacron and Teflon.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6181 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1485]

MEDICAL DEVICES

Classification of Intracardiac Patches and Pledgets Made of Polypropylene, Teflon, or Dacron

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intracardiac patches and pledgets made of polypropylene, Teflon, or Dacron into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intracardiac patches and pledgets made of polypropylene, Teflon, and Dacron:

1. Identification: An intracardiac patch or pledget made of polypropylene, Teflon, or Dacron is a fabric device placed in the heart that is used to repair septal defects, to patch grafting, to repair tissue, and to buttress sutures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Although the device is implanted, the Panel recommends that intracardiac patches and pledgets made of polypropylene, Teflon, or Dacron be classified into class II. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including properties such as porosity and tensile strength, should be maintianed at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this implanted device. Although the device is an implant, the Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel found further support for their recommendation in the medical literature. The following complications associated with this device are cited in the literature reviewed by the Panel: thromboembolism (Refs. 1 through 6); material or mechanical failure (Refs. 4, 5, and 7 through 11); hemolysis (Ref. 12); sarcoma (Ref. 13); and late infection (Ref. 14). Improper healing, including insufficient or excessive tissue ingrowth, is cited as a cause of patch or pledget rejection (Refs. 2, 4, and 6). Tissue reactions, such as inflammation, are common. However, patch or pledget rejection is rare (Ref. 15). Because nylon patches and pledgets caused loss of tensile strength, the use of nylon was abandoned (Refs. 5, 8, and 15). Thrombogenicity of the materials should be reduced to a minimum. However, all artificial materials are associated with some degree of blood incompatibility, and there is no agreement on the most effective means of reducing thrombogenicity. Guidoin (Ref. 16), for example, cites conflicting reports on the thrombogenicity of the Dacron used in different graft pros-

theses. For the materials now in use, it appears that artificial patches and pledgets perform as well as the alternative of autogenous tissue grafts.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Tissue and blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood and tissue may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that intracardiac patches and pledgets made of polypropylene, Teflon, or Dacron be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that, although the device is an implant, there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hansen, C. K., O. Kraft, and C. Mouritzen, "Biologic and Semibiologic Vascular Grafts," *Surgery, Gynecology, and Obstetrics*, 138:940–944, 1974.

2. Szilagyi, D. E., R. F. Smith, J. P. Elliot, and H. M. Allen, "Long-Term Behavior of a Dacron Arterial Substitute," *Annals of Surgery*, 162(3):453–477, 1965.

3. Berger, S. and E. W. Salzman, "Thromboembolic Complications of Prosthetic Devices," *Progress in Hemostasis and Thrombosis*, 2:273–309, 1974.

4. Hallin, R. W., "Complications with the Mandril-Grown (Sparks) Dacron Arterial Graft," *American Surgeon*, 41(9):550–554, 1975.

5. Szilagyi, D. E., J. R. Pfeifer, and F. J. DeRusso, "Long-Term Evaluation of Plastic Arterial Substitutes: An Experimental Study," *Surgery*, 55(1):165–183, 1964.

6. Sauvage, L. R., "The Future of Porous-Fabric Arterial Prostheses," *Annals of Thoracic Surgery*, 19:333–335, 1975.

7. Ottinger, L. W., R. C. Darling, R. S. Wuithlin, and R. R. Linton, "Failure of Ultralightweight Knitted Dacron Grafts in Arterial Reconstruction," *Archives of Surgery*, 111:146–149, 1976.

8. Lindenauer, S. M., T. R. Weber, T. A. Miller, S. R. Ramsbaugh, C. A. Salles, S. P. Kahn, and R. S. Wojtalik, "The Use of Velour as a Vascular Prosthesis," *Biomedical Engineering*, 11(9):301–306, 1976.

9. Deterling, R. A., "Editorial: Failure of Dacron Arterial Prostheses," *Archives of Surgery*, 108:13, 1974.

10. Cooke, P. A., P. A. Nobis, and R. J. Stoney, "Dacron Aortic Graft Failure," *Archives of Surgery*, 108:101–103, 1974.

11. Hayward, R. H. and F. L. Korompai, "Degeneration of Knitted Dacron Grafts," *Surgery*, 79(5):581–583, 1976.

12. Singh, A., E. A. Letsky, and J. Stark, "Hemolysis Following Correction of Double-Outlet Right Ventricle," *Journal of Thoracic and Cardiovascular Surgery*, 71(2):226–229, 1976.

13. O'Connell, T. X., H. J. Fee, and A. Golding, "Sarcoma Associated with Dacron Prosthetic Material," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):94–96, 1976.

14. Thompson, J., T. Dirksen, M. Nube, and A. G. Brom, "Prosthesis Endocarditis," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):28–32, 1976.

15. Transcript of Proceedings—Food and Drug Administration, Cardiovascular Device Panel Meeting, Washington, DC, Oct. 18, 1976, p. 166.

16. Guidoin, R. G., J. A. Awad, C. Gosselin, C. Rouleau, and G. H. Haggis, "Preclotting and Thrombosis of a Dacron Prosthesis: A Scanning Electron Microscope Study," *Biomaterials, Medical Devices, and Artificial Organs*, 3(3):365–382, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3470 as follows:

§870.3470 Intracardiac patch and pledget made of polypropylene, Teflon, or Dacron.

(a) *Identification.* An intracardiac patch or pledget made of polypropylene, Teflon, or Dacron is a fabric device placed in the heart that is used to repair septal defects, to patch grafting, to repair tissue, and to buttress sutures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6182 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1487]

MEDICAL DEVICES

Classification of Intra-Aortic Balloon and Control Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the intra-aortic balloon and control system into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification

of intra-aortic balloon and control systems:

1. Identification: An intra-aortic balloon and control system is a device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram (ECG), provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the intra-aortic balloon and control system be classified into class III because the device is life-supporting, and because the Panel believes that there is insufficient medical and scientific information to establish a standard to assure the safety and effectiveness of the device. The Panel stated that controversy exists as to whether the device is even beneficial in many situations in which it is used, and that it is difficult to use the device safely and effectively. The Panel believes that accurate and precise labeling and directions for use are especially critical. The Panel is concerned that the various components of the device would not function properly if its modular components were poorly matched. The balloon of the device is use within the main artery of intensive care patients to aid the heart in pumping blood throughout the body. Because this portion of the device is in contact with internal tissues and blood, the materials used with it require special controls. Because the device is typically electrically powered and portions of the device may be in direct contact with the heart, the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the design of the device is inadequate for accurate and precise blood pumping, a resulting failure could lead to death.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during placement or use of the balloon pump, and this may lead to iatrogenic complications. (b) Ineffective cardiac assist: Failure to sense or synchronize on heartbeat or failure to inflate and deflate at the proper intervals can lead to improper or ineffective pumping of blood. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanlinesss can lead to potentially debilitating or fatal thromboemboli. (d) Aortic rupture of dissection: Improper sizing or overinflation of the balloon can cause a rupture in the main artery. (e) Limb ischemia: Improper operation of the device which restricts blood flow to the peripheral vascular tree results in tissue ischemia (deficiency of blood supply to a portion of the body) in the limbs. (f) Gas embolism: Balloon rupture or a leak in the balloon can cause potentially debilitating or fatal gas emboli to escape into the bloodstream. (g) Hemolysis: Poor material-blood compatibility or excessive disruption of the normal hemodynamic flow patterns can cause hemolysis (destruction of red blood cells).

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the intra-aortic balloon and control system be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining blood circulation during certain types of heart failure) in supporting or sustaining human life. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371 (a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 807.3535 as follows:

§ 870.3535 Intra-aortic balloon and control system.

(a) *Identification.* An intra-aortic balloon and control system is a device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6183 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1488]

MEDICAL DEVICES

Classifiction of Ventricular Bypass (Assist) Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ventricular bypass (assist) devices into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will

issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION!

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of ventricular bypass (assist) devices:

1. Identification: A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. These devices are either totally or partially implanted in the body.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the ventricular bypass (assist) device be classified into class III because the device is an implant used in a life-supporting situation. It is powered by either a pneumatic, hydraulic, or electical source, and failure of the power source can lead to death. In addition, physical, chemical, and biological properties of materials used in the blood-contacting surfaces of the device have not been fully established, and there are divergent opinions about these materials. At this time, the device is primarily investigational. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance. For these reasons, the Panel believes that premarket approval is necessary to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, their personal knowledge of, and experience with, the device, and the experimental nature of the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli. (b) Excessive hemolysis: Poor design of the hemodynamic charactristics of the device can lead to excess hemolysis. (c) Inability to support life: Inaccurate pressure or flow control or improper synchronization can impede the ability of the device to support life. (d) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during the placement or use of the device, and this can lead to iatrogenic complications. (e) Interference with other organs: Because of its size and the location of its implantation, the device may interfere with the functioning of other organs. (f) Damage to blood vessels: The mechanical design of the attachments is associated with the possibility of damage to blood vessels at attachment points. (g) Inability to maintain long-term support: Low fatigue life of the materials used, or poor quality control in construction, can lead to premature breakdown of the device.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ventricular bypass (assist) device be classified into class III (premarket approval). The Commissioner notes the controversy surrounding the development of the left ventricular assist device, including differing philosophies among experts in the field involving optimum materials, hemodynamic performance, and power source. The Commissioner also cites the work presented on December 12-14, 1977, at the Devices and Technology Branch Contractor's Conference of the National Heart, Lung, and Blood Institute as indicative of the investigational nature of this device. This document is on file in the office of the Hearing Clerk, Food and Drug Administration. The Commissioner believes the device is purported or represented to be for a use (maintaining circulation in certain case of heart failure) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3545 as follows:

§ 870.3545 Ventricular bypass (assist) devices.

(a) *Identification.* A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. These devices are either totally or partially implanted in the body.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6184 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1489]

MEDICAL DEVICES

Classification of External Pacemaker Pulse Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external pacemaker pulse generators into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external pacemaker pulse generators:

1. Identification: An external pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that external pacemaker pulse generators be classified into class III because the device provides temporary life-support. The Panel believes that premarket approval is necessary to assure its safety and effectiveness. The device is in contact with the patient's heart through a pacemaker electrode catheter. Certain kinds of failure could cause this device to emit inappropriate electrical signals, which could cause cardiac irregularities and death. Failure of the power source, usually a battery, could lead to cardiac standstill or other pacing irregularities. Although the device may be in contact with the patient's skin, the materials that touch the patient are generally acceptable and require no additional controls. Performance characteristics, including accuracy, reproducibility, and any limitations on the rate and level of the output stimuli and the input sensitivity of the device, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, their personal knowledge of, and experience with, the device, and its life-supporting function.

5. Risks to health: (a) Failure to pace: A failure of the electronic circuitry can cause failure to pace the patient's heart. (b) Improper pacing: Electromagnetic interference with the pacemaker electronics or improper sensing by the pacemaker can lead to improper pacing. (c) Cardiac arrythmias: Pacing during vulnerable periods of the cardiac cycle due to a sensing failure of the pacemaker can induce cardiac arrythmias. (d) Improper pacing rate: An electronic circuit failure or an inaccurate rate controller in the circuit can cause improper pacing rates.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the external pacemaker pulse generator be classified into class III (Premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. the Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3600 as follows:

§ 870.3600 External pacemaker pulse generator.

(a) *Identification.* An external pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse stength, duration, R-wave sensitivity, and other pacing variables.

(b) *Classification.* class III (premarket approval).

Interested persons may, on or before (*insert date 60 days after date of publication in the* FEDERAL REGISTER) submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit

single copies of comments, and shall be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6185 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1490]

MEDICAL DEVICES

Classification of Implantable Pacemaker Pulse Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implantable pacemaker pulse generators into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implantable pacemaker pulse generators:

1. Identification: An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This generic term includes triggered, inhibited, and asynchronous devices implanted in the human body.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the implantable pacemaker pulse generator be classified in class III because the device is implanted and life-supporting and presents a potential unreasonable risk of illness or injury. This device is intended to be used over a period of years to pace a heart with a natural pacing defect. It is surgically implanted in patients with heart pacing or conduction defects. The patients may be totally dependent upon this device for their continued survival. The Panel states that, although a proposed standard has been written, it does not cover all the performance characteristics of the device. The Panel noted further that the proposed standard is not widely accepted. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of the device. In addition, the Panel believes that sufficient scientific and medical data do not exist to establish a complete standard to assure the safety and effectiveness of particular aspects of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, their personal knowledge of and experience with the device, and the life-supporting function of the device.

5. Risks to health: (a) Failure to pace: A failure of the electronic circuitry or early battery depletion can cause failure to pace the patient's heart. (b) Improper pacing cycle: Electromagnetic interference with pacemaker electronics or improper sensing by the pacemaker can lead to improper pacing. (c) Arrhythmias: A sensing failure of the pacemaker during vulnerable periods of the cardiac cycle can induce cardiac arrhythmias. (d) Improper pacing rate: An electronic circuit failure or an inaccurate rate controller in the circuit can cause improper pacing rates. (e) Tissue damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the local tissue may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the implantable pacemaker pulse generator be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3610 as follows:

§ 870.3610 Implantable pacemaker pulse generator.

(a) *Identification.* An implantable pacemaker pulse generator is a device that has power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continous cardiac rhythm disorders. This generic term includes triggered, inhibited, and asynchronous devices implanted in the human body.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6186 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1491]

MEDICAL DEVICES

Classification of Pacemaker Lead Adaptors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker lead adaptors into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glen A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of pacemaker lead adaptors:

1. Identification: A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The panel recommends that the pacemaker lead adaptor be clasified into class III because the device is implanted, life-supporting, and presents a potential unreasonable risk of illness or injury. This device electrically and mechanically connects a pacemaker lead to a different manufacturer's pacemaker. It serves a vital purpose and is generally used when a pacemaker is replaced by another pacemaker made by a different manufacturer. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that the device can create a hazard to the life of the patient if it is not manufactured or employed properly. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that there are insufficient medical, engineering, and scientific data to establish a performance standard to assure the safety and effectiveness of this life-supporting device, and, therefore, that premarket approval is necessary.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, their personal knowledge of, and experience with, the device, and the life-supporting function of the device.

5. Risks to health: (a) Improper pacing: Poor mehancial or electrical design could cause a failure to properly pace the patient's heart. (b) Failure to pace: Electrical or mechanical incompatibility leading to conductor breakage or electrochemical corrosion can cause failure to pace the patient's heart. Also, the use of poor sealant materials that allow water to enter into the electrical junction between the pacemaker and its pacing lead diverts the current from the heart and causes failure to pace. (c) Tissue damage: Insufficiently biocompatible materials can lead to adverse tissue reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker lead adaptor be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performace standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3620 as follows:

§ 870.3620 Pacemaker lead adaptor.

(a) *Identification.* A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs

[FR. Doc. 79-6187 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1492]

MEDICAL DEVICES

Classification of Pacemaker Generator Function Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker generator analyzers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker generator function analyzers:

1. Identification: A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that pacemaker generator function analyzers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Failure of the device to perform its analysis function may lead to improper cardiac pacing or cardiac arrythias. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of pacemaker generator function, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or improper pacing: Inability of the device to accurately measure the pacemaker's performance parameters may result in the implantation of an inappropriate or poorly functioning pacemaker.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker generator function analyzer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3630 as follows:

§ 870.3630 Pacemaker generator function analyzers.

(a) *Identification.* A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold.

(b) *Classification.* Class II (performance standards).

Interested persons, may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6188 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1493]

MEDICAL DEVICES

Classification of Indirect Pacemaker Generator Function Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY. The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying indirect pacemaker generator function analyzers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the

device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of indirect pacemaker generator function analyzers:

1. Identification: An indirect pacemaker generator function analyzer is an electrically powered device that is used to determine pacemaker function or pacemaker battery function by periodically monitoring an implanted pacemaker's pulse rate and pulse width. The device is noninvasive, and it detects pacemaker pulse rate and width via external electrodes in contact with the patient's skin.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the indirect pacemaker generator function analyzer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through surface electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Failure of the device to perform its analysis function may lead to improper cardiac pacing or cardiac arrythmias. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of pacemaker generator function, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, which can lead to onset of cardiac arrhythmias. (b) Misdiagnosis: Inadequate design of the device affecting its ability to sense pacemaker generator function can lead to inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the indirect pacemaker generator function analyzer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health.

A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3640 as follows:

§ 870.3640 Indirect pacemaker generator function analyzer.

(a) *Identification.* An indirect pacemaker generator function analyzer is an electrically powered device that is used to determine pacemaker function or pacemaker battery function by periodically monitoring an implanted pacemaker's pulse rate and pulse width. The device is noninvasive, and it detects pacemaker pulse rate and width via external electrodes in contact with the patient's skin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979. Submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6189 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1494]

MEDICAL DEVICES

Classification of Pacemaker Polymeric Mesh Bags

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker polymeric mesh bags into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker polymeric mesh bags:

1. Identification: A pacemaker polymeric mesh bag is a device used to hold a pacemaker pulse generator. It is designed to create a stable implant environment for the generator.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the pacemaker polymeric mesh bag be classified into class II because this implanted device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel reviewed the following information from the medical literature. The fabric mesh bag used with a cardiac pacemaker takes advantage of tissue ingrowth to stabilize, and to prevent migration of, the pacemaker generator. While the phenomenon of tissue ingrowth into porous materials is well-known, it is usually described in passing without great detail and is not reported in controlled studies. Lee and Neville (Ref. 1) claim that, as of 1971, internal mounting of artificial organs had received no specific attention in the medical literature. However, both Wesolowski (Ref. 2), in 1962, and Braunwald and Bull (Ref. 3), in 1969, indicated that an increase in porosity of fabrics increases the ingrowth activity in either vascular graft prostheses or artificial heart valves. Lindenauer et al. (Ref. 4) also indicated better tissue ingrowth in more porous materials, and cited a leak-rate porosity value and tissue ingrowth correlation. In general, the vascular graft literature recognizes and discusses tissue ingrowth. Many uses of fabrics for tissue fixation have been listed by Lee and Neville (Ref. 1), including heart valves, vascular grafts, tracheal tube grafts, artificial tendons, percutaneous A-V shunt seals, and artificial breasts among many other applications. Some other concerns expressed by Skelton (Ref. 5) included specification of polymeric composition and additives and fabric configuration (i.e., weave, knit, velour, etc.). These concerns are also being addressed by various voluntary standards groups.

5. Risks to health: Tissue damage: Tissue damage can occur by an adverse reaction to the material, infection, tearing of tissue, mechanical failure of the bag, and failure of the bag to contain or restrain the pacemaker.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker polymeric mesh bag be classified into class II (performance standards). In arriving at this decision the Commissioner has reviewed additional information from the medical literature and has found that the phenomenon of tissue ingrowth into porous implanted material is well characterized in controlled animal studies and well documented in clinical experience. The phenomenon has been utilized in fixation and stabilization of prostheses in vascular surgery (Ref. 2), heart valve replacement (Ref. 3), intraocular lens replacement (Ref. 6), muscle and tendon repair (Refs. 7 and 8), artificial joints in bone (Refs. 7 and 8), and percutaneous vascular access (Ref. 9). The rate of tissue ingrowth in relation to time, pore size, and percent porosity of the implant was studies and reported by Hulbert et al. (Ref. 8). Brais and Braunwald (Ref. 10) reported on a method for accelerating and controlling and rate of tissue ingrowth into fabrics implanted in the heart. Dunn et al. (Ref. 7) demonstrated the mechanical strength of the matrix formed by the porous implant material and the ingrown tissue. Electron microscopic scanning (Refs. 11 and 12) and histologic examination (Refs. 7, 9, 10, and 13) of porous materials implanted in various tissues, including bone, muscle and soft tissue, have thoroughly demonstrated the ingrowth of tissue into porous prostheses, and the mechanical testing of ingrown tissue (Refs. 7 and 8) has proven the value of this phenomenon in fixation and stabilization of prostheses. The phenomenon of tissue ingrowth has even provided a means for the development and investigation of autologous arterial grafts (grafts in which the donor and recipient are the same individual) by growing fibrous tissue in a porous fabric surrounding a solid plastic mold (Ref. 14). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that, although the device is an implant, there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadena, Calif., 1971, pp. 6-57 to 6-63.

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14. Sawatani, S., C. Mandell, I. Kiso, and A. Kantrowitz, "Antologous Arterial Grafts Grown on Polyester Molds: Observations of Graft Growth and Patency in Experimental Animals," *Journal of Cardiovascular Surgery (Torino)*, 18(1):63-70, 1977.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3650 as follows:

§ 870.3650 Pacemaker polymeric mesh bag.

(a) *Identification.* A pacemaker polymeric mesh bag is a device used to hold a pacemaker pulse generator that is designed to create a stable implant environment for the pulse generator.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food, and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Recieved comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner, for Regulatory Affairs.

[FR Doc. 79-6190 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1496]

MEDICAL DEVICES

Classification of Pacemaker Chargers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker chargers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of pacemaker chargers:

1. Identification: A pacemaker charger is a device used transcutaneously to recharge the batteries of a rechargeable pacemaker.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pacemaker chargers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached directly to the surface of the body and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's recharging capability, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Pacemaker slowly stops functioning: Failure of the device to recharge the battery or a misindication of the amount of recharging can cause the pacemaker to fail prematurely due to battery depletion. (c) Tissue burn: Thermal burns to the tissues adjacent to the pacemaker can result from overcharging by the device. (d) Failure of the pacemaker: Overcharging by the device can lead to damage to the pacemaker and result in pacemaker failure.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker charger be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commis-

sioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectivenes of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3670 as follows:

§ 870.3670 Pacemaker charger.

(a) *Identification.* A pacemaker charger is a device used transcutaneously to recharge the batteries of a rechargeable pacemaker.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6191 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1497]

MEDICAL DEVICES

Classification of Permanent and Temporary Pacemaker Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying permanent and temporary pacemaker electrodes into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Dureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of permanent and temporary pacemaker electrodes:

1. Identification: Permanent and temporary pacemaker electrodes are flexible insulated electrical conductors with one end connected to a pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that permanent and temporary pacemaker electrodes be classified into class III because this device is life-sustaining, and there is insufficient scientific and medical data to develop a standard to assure the safety and effectiveness of the device. The electrode is implanted into the body and can be in direct contact with the blood. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device provides an electrical path between a pacemaker and the heart. An interruption or short circuit of this path could interfere with proper pacing of the heart. Certain characteristics of the device must be maintained by proper construction and storage. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. The Panel found further support for their recommendation in the medical literature. The electrode lead transmits the electrical signal from the pulse generator to the heart and directly stimulates the myocardium. Several varieties of electrode design are used to fulfill the role of the electrode lead. The two basic categories of electrodes are endocardial and myocardial. More than 90 percent (Ref. 1) of all pacemaker implants use the endocardial type. Although they are of two general types (bipolar and monopolar), endocardial electrode leads are of a number of geometrical configuration designed to reduce the current drain per pulse and to avoid electrode displacement and corrosion. Some experimental endocardial electrodes, such as the differential current density electrode and the capacitor electrode, have been developed to minimize electrode corrosion and tissue reaction problems. Myocardial electrode leads also are available in many forms, including corkscrew-mesh and suture types, which are secured by sutures or a combination of electrode screw-in and tissue ingrowth into the mesh. Myocardial electrode leads can be used alone as a monopolar system, or in pairs as a bipolar system, and they can be made in bipolar single lead form. The terms monopolar and bipolar actually refer to the number of poles located at the heart and not to the total number of poles, since all pacemakers have both a cathode and an anode. In the monopolar system the cathode is on the lead at the heart and the anode is a metal plate on the generator package. The medical literature lists the following materials used in pacemaker electrodes and leads: cardiac electrodes—platium-iridium and cobalt-nickel (Elgiloy); generator anode—stainless steel titanium; lead wires—stainless steel and platinum-iridium; lead insulation—silicone rubber and Teflon. Lead wires are usually manufactured from various forms of multiple helical coils or multiple strands to reduce breakage by distributing stress during flexion throughout the wire

and, by providing redundancy, preventing a single break from causing conduction failure. The complication most frequently listed in the medical literature is lead fracture (refs. 1 through 4, 6 through 8, 11, and 16), which is sometimes broken down into wire breakage and insulation breakage. Roy (Ref. 1) discusses the use of helically coiled wires to increase the longevity of pacemaker leads, but states that the optimum design has not yet been determined in clinical trials. With increasing battery life, leads will need to withstand an increased number of flexion cycles and may need to be redesigned to ensure safety. Grogler, et al., (Ref. 2) indicates a lead breakage rate of 6.6 percent in endocardial leads; Green (Ref. 7) indicates a breakage rate of 23.4 percent for an older lead design and 1.2 percent for a lead of more recent design. Another problem frequently mentioned in the medical literature is electrode displacement (Refs. 2 through 4, 7, 8, 14, and 16). Although the configuration of the lead can be designed so that displacement is reduced, improper placement at the time of surgery can also cause displacement (Ref. 4). Hence, this problem is complexly related to both design and operative procedure. Grogler's (Ref. 2) results indicate a dislocation rate of 11 percent. Related to electrode displacement is the problem of diaphragmatic contractions, which can be caused by a malpositioned electrode stimulating the phrenic nerve (Refs. 2 and 4). The third most commonly cited complication is "exit block" (Refs. 2 through 4, 6, 7, 14, and 16), which is the failure to achieve pacing due to a rise in the stimulation threshold to a current value above the generator's current output. This condition is caused by the natural development of a nonexcitable, fibrous tissue sheath around the electrode tip. Threshold rise occurs after all electrode implantations and usually levels off after approximately 2 weeks (Ref. 1). If the sheath that is formed can be minimized, then threshold rise is also reduced and "exit block" can be reduced in turn. Grogler's (Ref. 2) results indicate that "exit block" occurs 1.6 percent of the time; Green (Ref. 7) shows "exit blocks" of 1 to 8 percent for endocardial leads and 5 to 6 percent for myocardial leads. Green's 8 percent figure is for an older electrode design; the newer designs tested showed a 1 to 2 percent incidence of "exit block." Another complication listed in the literature is cardiac perforation (Refs. 2, 4, 6, 8, 13, and 14). Its incidence is reported to be between 0.7 percent (Ref. 2) and 7.1 percent (Ref. 4). Perforation has also been reported to lead to diaphragm contractions (Ref. 6). Infection is generally listed as an electrode complication (Refs. 4, 6, 8, and 10), although this problem is usually surgical (Ref. 2). Other problems less frequently mentioned are knotting of lead wire (Ref. 6), corrosion leading to gas generation at the electrodes (Refs. 1 and 9), arrhythmias (Refs. 6 and 8), thrombosis (Refs. 2 and 6), and subepicardial infarction (Ref. 13). Small surface area electrodes used in demand pacing have been found to fail to sense properly and thus cause loss of pacing (Ref. 12). Although these problems are less common, they can cause serious complications. For example, thromboitic developments can easily become emboli leading to pulmonary infarction. In summary, there are many problems in cardiac pacing that are directly or indirectly related to electrode lead design. Grogler (Ref. 2) has reported lead complications, not including infection, in 20.4 percent of the 770 endocardial leads used in that study. It has been shown that small surface area electrodes reduce the threshold current, thus reducing current drain and increasing pacer life. However, Hughes, et al. (Ref. 12), have reported that these same electrodes, when used with demand pacemakers, can fail to sense demand properly and cause loss of pacing. This would indicate a strong need for matching electrode to generator. Currently proposed standards (Ref. 16) merely address dimensions and dimensional tolerances, and performance limits as tested by various accelerated bench tests. These proposals do not deal with lead displacement, cardiac perforation, "exit block," thrombosis, and other complications that comprise 13.8 percent of the complications noted in Grogler's study (Ref. 2). In discussing electrode lead choice, Roy (Ref. 1) states, "Accelerated bench testing cannot duplicate all the in situ conditions. To a large extent, the choice awaits long term in vivo statistics." The Panel concluded from the literature that clinical and preclinical studies to establish the safety and effectiveness of electrode lead designs are necessary.

5. Risks to health: (a) Loss of pacing: Poor mechanical and material properties can cause lead breakage. Improper electrical impedance of the lead can cause inadequate sensing or pulse delivery. Either of these conditions leads to loss of pacing of the patient's heart. (b) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli. (c) Improper pacing: Tissue reactions at the electrode tissue interface can cause a rise in pacing threshold and lead to loss of or improper pacing function by causing "exit block."

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the permanent and temporary pacemaker electrode be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Roy, O. Z. "The Current Status of Cardiac Pacing," *CRC Critical Reviews in Bioengineering*, 2(3):259-327, 1975.

2. Grogler, F. M., G. Frank, G. Greven, D. Dragojevic, H. Oelert, K. Leitz, H. Dalichau, U. Brinke, D. Lohlein, D. Rogge, R. Hetzer, G. Hennersdorf, H. G. Borst, "Complication of Permanent Transvenous Cardiac Pacing," *Journal of Thoracic and Cardiovasular Surgery*, 69(6): 395-404, 1975.

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5. Furman, S., J. Garvey, P. Hurzeler, "Pulse Duration Variation and Electrode Size of Factors in Pacemaker Longevity," *Journal of Thoracic and Cardiovascular Surgery*, 69(3): 382-389, 1975.

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10. Yarnoz, M. D., L. A. Attal, S. Furman, "Infection of Pacemaker Electrode and Removal with Cardiopulmonary Bypass," *Journal of Thoracic and Cardiovascular Surgery*, 69(1):43-46, 1974.

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13. Steinke, W. E., F. T. Thomas, Z. Hassan, R. A. Mandeza, A. S. Grea, "Subepicardial Infarction, Myocardial Impression, and Ventricular Penetration by Sutureless Electrode and Leads," *Chest*, 70(1):80-81, 1976.

14. Magilligan, D. J., J. Hakimi, J. C. Davila, "The Sutureless Electrode: Comparison with Transvenous and Sutured Epicardial Electrode Placement for Permanent Pacing," *Annals of Thoracic Surgery*, 22(1):80-86, 1976.

15. Shammash, J. B., Letter: "The Sutureless Electrode," *Annals of Thoraic Surgery*, 22(1):104-105, 1976.

16. Implantable Pacemaker Literature Summaries, Association for the Advancement of Medical Instrumentation, Arlington, Va., FDA Contract No 223-74-5083, January 1975.

17. Pacemaker Standard, Association for the Advancement of Medical Instrumentation, Arlington, Va., FDA Contract No. 223-74-5083, August 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3680 as follows:

§ 870.3680 Permanent and temporary pacemaker electrode.

(a) *Identification.* Permanent and temporary pacemaker electrodes are flexible insulated electrical conductors with one end connected to a pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulas from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

(b) *Classification.* Class III (premarket approval.)

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6192 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1498]

MEDICAL DEVICES

Classification of Pacemaker Test Magnets

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker test magnets into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker test magnets:

1. Identification: A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: Although the device is life-sustaining under certain circumstances, the Panel recommends that the pacemaker test magnet be classified into class II. During an operation in which a patient's triggered or inhibited pacemaker might receive stray electrical signals from electrosurgical devices, for example, the reversion magnet assumes a life-sustaining role by preventing interference from disrupting the steady output of the pacemaker. The magnetic strength must be adequate to switch reliably an implanted triggered or inhibited pacemaker to asynchronous operation. This is usually done by closing a reed switch within the pacemaker. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel found further support for their recommendation in the medical literature. The risks cited in the literature reviewed by the Panel are failure of the magnet to cause the pacemaker to revert to a fixed rate (Refs. 1 and 2) and inducement of ventricular fibrillation (Ref. 3). The latter was probably caused by faulty pacemaker design. The former is of greater concern here because, although it is possible that failure to revert may be due to an insensitive pacemaker, it may be directly attributable to the properties of the magnet itself.

5. Risks to health: (a) Misdiagnosis: Inadequate design of the device with regard to magnetic strength can lead to inaccurate assessment of pacemaker function. If an inaccurate assessment of pacemaker function is used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily. (b) Improper pacemaker operation: When a magnet is used to induce continuous operation of the pacemaker

during surgery, failure to revert may be life-threatening.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the pacemaker test magnet be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that, although the device can be life-supporting, there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Driller, J., S. S. Barold, and V. Parsonnet, "Normal and Abnormal Function of the Pacemaker Magnetic Reed Switch," *Journal of Electrocardiology*, 9(3):283-292, 1976.

2. Barold, S. S., "Current Problems with Demand Pacemakers," *European Journal of Cardiology*, 1(4):339-345, 1974.

3. Seipel, L., E. Bub, and S. Driwas, "Ventricular Fibrillation During Testing of a Demand Pacemaker," *Deutsch Medizinische Wochenschrift*, 100(47):2437-2442, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3690 as follows:

§ 870.3690 Pacemaker test magnet.

(a) *Identification.* A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6193 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1499]

MEDICAL DEVICES

Classification of Pacemaker Programmers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker programmers into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker programmers:

1. Identification: A pacemaker programmer is a device used to change noninvasively one or more of the electrical operating characteristics of a pacemaker.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: Because the Panel recommends that pacemakers be classified into class III, they also recommend class III for pacemaker programmers. The Panel believes that premarket approval is necessary to assure the safety and effectiveness of this life-supporting device. The Panel noted that because this device must be designed to operate with a specific pacemaker as a system, the same level of control is necessary for both devices. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there are insufficient data to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Improper pacemaker operation: Inadequate design of the device's programming function can cause the pacemaker to lose its sensing or pacing ability, or to pace at an improper rate. (c) Misdiagnosis: Inadequate design of the device's ability to sense pacemaker function can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (d) Inability to change pacing therapy: Inadequate matching of the programmer to the pacemaker could lead to a situation where the pacemaker could not be programmed, thereby preventing a needed change in pacing therapy and placing the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is pro-

posing that the pacemaker programmer be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. The Commissioner also believes the device is purported or represented to be for a use in controlling the electrical output of a programmable implanted pacemaker which is of substantial importance in preventing impairment of human health. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3700 as follows:

§ 870.3700 Pacemaker programmer.

(a) *Identification.* A pacemaker programmer is a device used to change noninvasively one or more of the electrical operating characteristics of a pacemaker.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6194 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1500]

MEDICAL DEVICES

Classification of Pacemaker Repair and Replacement Materials

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker repair and replacement materials into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker repair and replacement materials:

1. Identification: Pacemaker repair and replacement materials are adhesives, sealants, screws, crimps, and other materials used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that pacemaker repair and replacement materials be classified into Class III because these materials are implanted in the human body and serve to connect or aid in the connection of the vital link between a pacemaker pulse generator and a pacemaker lead. The connection function of the device is life-supporting because it maintains the conduction of the pacing pulse. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance. The Panel believes that premarket approval is necessary to assure the safety and effectiveness of this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, the life-supporting function of this implanted device, and their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue damage: If the biocompatibility of the materials used in this device is inadequate, damage to the surrounding tissue may result. (b) Loss of pacing function: Failure to seal the lead properly could allow the intrusion of fluid into the pacemaker connection. This could in turn lead to a loss of pacing function through electrical leakage at the connector or through an interruption of the electrical path from the pulse generator to the lead.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker repair and replacement materials be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is

not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3710 as follows:

§ 870.3710 Pacemaker repair and replacement materials.

(a) *Identification.* Pacemaker repair and replacement materials are adhesives, sealants, screws, crimps, and other materials used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 29857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6195 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1501]

MEDICAL DEVICES

Classification of Pacemaker Electrode Function Testers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker electrode function testers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glen A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committe, made the following recommendation with respect to the classification of pacemaker electrode function testers:

1. Identification: A pacemaker electrode function tester is a device which is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and the intracardiac R-wave potential.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The panel recommends that pacemaker electrode function testers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly use. Failure of the device to accurately measure pacing threshold can lead to pacing failures due to excessive or insufficient charge, energy, or current delivered through the electrode. This device is attached to the body through the pacemaker electrode lead and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics including accuracy and reproducibility and any limitations on the device's ability to measure pacing threshold and R-wave amplitude should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Although the device releases an acceptable level of energy into the body when functioning properly, unsafe energy levels may be released if the device malfunctions. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Cardiac arrhythmias: Excessive charge, energy, or current supplied to the heart because of inaccurate calibration, or a sensing failure (for inhibited type pacemakers) due to inaccurate calibration, can result in cardiac arrhythmias. Also, excessive electrical leakage current can disturb the normal electrophysiology of the heart, thus leading to the onset of cardiac arrhythmias.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker electrode function tester be classified into class II (performance standards). The Commissioner believes that performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance stand-

ard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3720 as follows:

§ 870.3720 Pacemaker electrode function tester.

(a) *Identification.* A pacemaker electrode function tester is a device which is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and the intracardiac R-wave potential.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6196 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1502]

MEDICAL DEVICES

Classification of Pacemaker Service Tools

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker service tools into class I (general controls). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker service tools:

1. Identification: Pacemaker service tools are devices, such as screwdrivers and Allen wrenches, used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker generator.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemption.

3. Summary of reasons for recommendation: The Panel recommends that pacemaker service tools be classified into class I because the device is composed of a variety of mechanical tools that are neither life-sustaining nor life-supporting and present no potential hazard to health when properly used. The materials used in the device are generally acceptable and need no special control requirements. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which recommendation is based: the Panel based its recommendation upon the lack of potential hazards associated with the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that pacemaker service tools be classified into class I (general controls). The Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3730 as follows:

§ 870.3730 Pacemaker service tools.

(a) *Identification.* Pacemaker service tools are devices such as screwdrivers and Allen wrenches, used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker generator.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6197 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1503]

MEDICAL DEVICES

Classification of Annuloplasty Rings

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying annuloplasty rings into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the

device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes; that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Wefare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of annuloplasty rings:

1. Identification: An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the annuloplasty ring be classified into class III because the device is implanted and is life-supporting. The Panel believes that premarket approval is necessary to assure the safety and effectiveness of this implanted device. The device is used for correction of valvular insufficiency and, if not designed properly, it presents a potential unreasonable risk of illness, injury, or death. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue and blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood and tissue may result. (b) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (c) Embolism: Pieces of the ring that break or flake off may form potentially debilitating or fatal emboli. (d) Dilation of the heart eventually leading to intractable heart failure: If the mechanical design of the device does not provide an adequate means of correcting valvular insufficiency the condition will persist causing dilation of the heart and eventually leading to intractable heart failure.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the annuloplasty ring be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (correction of heart valve insufficiency) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 70(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3800 as follows:

§ 870.3800 **Annuloplasty ring.**

(a) *Identification.* An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.

(b) *Classification.* Class III (premarket approval.)

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6198 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1504]

MEDICAL DEVICES

Classification of Carotid Sinus Nerve Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carotid sinus nerve stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of carotid sinus nerve stimulators:

1. Identification: A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the carotid sinus nerve stimulator be classified into class III because, although this device is neither life-supporting nor life-sustaining, it presents a potential unreasonable risk to life or health even when properly used and because it is an implant. A carotid sinus nerve stimulator typically consists of an implanted stimulator with electrodes in contact with the carotid sinus nerve. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device presents some potential hazards either by electrical shock or through failure to perform as a result of a power source failure. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to reduce blood pressure by Hering's nerve stimulation, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue and blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood and tissue may result. (b) Inability to control blood pressure: Failure of the device to stimulate properly can prevent effective control of elevated blood pressure.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the carotid sinus nerve stimulator be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use in controlling chronic high blood pressure, which is of substantial importance in preventing impairment of human health. The device is intended to be implanted in the human body. The act requires the Commissioner to classify an implant into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Stephenson, H. E., "Cardiac Arrest and Resuscitation," C. V. Mosley Co., St. Louis, pp. 413-414, 1974.

2. Levy, M. N. and Zieske, "Factorial Analysis of the Cardiovascular Response to Carotid Sinus Nerve Stimulation," *Annals of Biomedical Engineering*, 4:111-127, 1976.

3. Schwartz, S. I., L. S. C. Griffith, A. Neistadt, and N. Hagfors, "Chronic Carotid Sinus Nerve Stimulation in the Treatment of Essential Hypertension," *American Journal of Surgery*, 114:5-15, 1967.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3850 as follows:

§ 870.3850 **Carotid sinus nerve stimulator.**

(a) *Identification.* A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6199 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1505]

MEDICAL DEVICES

Classification of Replacement Heart Valves

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying replacement heart valves into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device be classified into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. The actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of replacement heart valves:

1. Identification: A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This generic device class includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device by a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the replacement heart valve be classified into class III because this device is an implant that is life-supporting and life-sustaining. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including blood flow properties and mechanical strength, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device, that there is not sufficient information to establish a standard to provide such assurance and, therefore, that premarket approval is necessary for this device.

4. Summary of data on which recommendation is based: the Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel found further support for their recommendation in the medical literature. Because the Panel conducted an extensive literature search in the medical literature, only a small sample of the literature reviewed is cited here (Refs. 1 through 10).

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surfact finish and cleaniness may lead to potentially debilitating or fatal thromboemboli. (b) Excessive regurgitation, excessive hemolysis, improper hemodynamic operation, excessive obstruction, and valve degeneration: Poor valve design can cause one or more of these conditions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the replacement heart valve be classified into class III) premarket approval).

The Commissioner believes the device is purported or represented to be for a use (correction of heart valve defects) in supporting or sustaining human health. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Chun, P. K. C. and W. P. Nelson, "Common Cardiac Prosthetic Valves," *Journal of the American Medical Association*, 238(5):401-403, 1977.

2. Cuddihy, E. F., et al., "In Vivo Degradation of Silicone Rubber Poppets in Prosthetic Heart Valves," *Journal of Biomedical Materials Research*, 10:471-481, 1976.

3. Elster, S. K., et al., "Hemophilus Aphrophilus Endocarditis: Review of 23 Cases," *American Journal of Cardiology*, 35:72-79, 1975.

4. Bristion, J. D. and E. L. Kremkaw, "Hemodynamic Changes after Value Replacement with Starr-Edwards Prosthesis," *American Journal of Cardiology*, 35:716-724, 1975.

5. Lee, S. J. K., et al., "Long-Term Survival After Aortic Value Replacement Using Smeloff-Cutter Prosthesis," *Circulation*, 52:1132-1137, 1975.

6. Kloster, F. E., "Diagnosis and Management of Complications of Prosthetic Heart Valves," *American Journal of Cardiology*, 35:875-885, 1975.

7. Roberts, W. C., M. G. Fishbein, and A. Golden, "Cardiac Pathology After Valve Replacement by Disc Prosthesis," *American Journal of Cardiology*, 35:740-760, 1975.

8. Ionescu, M. I., et al., "Long-Term Evaluation of Tissue Valves," *Journal of Thoracic and Cardiovascular Surgery*, 68(3):361-379, 1974.

9. Suwansirikul, S., et al., "Late Thrombosis of Starr-Edwards Tricuspial Ball Valve Prosthesis," *American Journal of Cardiology*, 34:737-740, 1974.

10. Bjork, V. O., A. Henze, and A. Holmgren, "Five Year's Experience with the Bjork-Shiley Tilting Disc Valve in Isolated Aortic Valvular Disease," *Journal of Thoracic and Cardiovascular Surgery*, 68(3):393-404, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3925 as follows:

§ 870.3925 **Replacement heart valve.**

(a) *Identification.* A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This generic device class includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valve), or valves constructed of a combination of prosthetic and biologic materials.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6200 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1506]

MEDICAL DEVICES

Classification of Prosthetic Heart Valve Holders

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prosthetic heart valve holders into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Wefare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of prosthetic heart valve holders:

1. Identification: A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the prosthetic heart valve holder be classified into class II because the device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. The device is used with other devices in a system that may be hazardous if not assembled, used, and maintained in a satisfactory fashion. The device should be designed so that it will not cause damage to the replacement heart valve. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Valve failure: Replacement valve damage, causing the valve to function improperly or to have a shortened service life, can be caused by poor mechanical design of the valve holder and by use of incompatible materials for the valve and valve holder. If the replacement valve is damaged, valve failure and the necessity for a hazardous corrective reoperation may occur.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the prosthetic heart valve holder be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although prosthetic heart valve holders are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3935 as follows:

§ 870.3935 Prosthetic heart valve holder.

(a) *Identification.* A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6201 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1507]

MEDICAL DEVICES

Classification of Prosthetic Heart Valve Sizers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prosthetic heart valve sizers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of prosthetic heart valve sizers:

1. Identification: A prosthetic heart valve sizer is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that heart valve sizers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise determination of proper valve size, the resulting misdiagnosis could have a significant negative effect on the patient's health. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to measure heart valve size should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Implantation of an inappropriate size valve: The valve sizer should reflect the total diameter of the valve, including the sewing collar and the diameter of the valve orifice, with sufficient dimensional accuracy and tolerance to protect against implantation of an improperly sized valve.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the prosthetic heart valve sizer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although prosthetic valve sizers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3945 as follows:

§ 870.3945 Prosthetic heart valve sizer.

(a) *Identification.* A prosthetic heart valve sizer is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve.

(b) *Classification.* Class II (performance standards).

Interested persons may, or or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Land, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6202 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1508]

MEDICAL DEVICES

Classification of Endomyocardial Biopsy Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endomyocardial biopsy devices into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of endomyocardial biopsy devices:

1. Identification: An endomyocardial biopsy device is a device used to

remove samples of tissue from the inner wall of the heart.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendaton: The Panel recommends that the endomyocardial biopsy device be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including any limitations on the device's ability to safely obtain a biopsy specimen, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel found further support for their recommendation in the medical literature. Use of an endomyocardial biopsy device was first described by Sakakibara and Konno in 1962 (Ref. 1). Since that time, the device has been modified by others (Refs. 2 through 5). Introduction of an endomyocardial biopsy device involves the insertion of a bioptome (an instrument for removing a small fragment of tissue) via a percutaneous catheter to the desired endomyocardial site in either the right or left heart (Refs. 1 through 10). The procedure of biopsy holds an established place in medical practice, and the efficacy of this biopsy device does not appear to be questioned (Refs. 1 through 10). The most serious hazards associated with the use of this biopsy device are perforation into and hemorrhage of the endomyocardial wall (Refs. 6 through 8). Tricuspid perforation has been reported in dogs (Ref. 8). Perforation and hemorrhage can be accompanied by pericardial tamponade (compression of the heart due to accumulation of fluid within the sac surrounding the heart) (Refs. 7 and 8), which is an immediate life-threatening complication. These hazards are predominately user-related and occur most frequently when the bioptome is advanced to the endomyocardial wall with its jaws closed. This configuration apparently renders the shape of the bioptome "bulletlike" and permits endomyocardial entry even when minimal pressure is applied (Ref. 6). The incidence of perforation and hemorrhage is significantly reduced by advancing the bioptome with its jaws open. Other hazards associated with the use of this device are embolization and transient chest pain (Refs. 4, 5, and 7). The incidence of embolization is apparently lower in patients who are receiving anticoagulant drugs (Refs. 5 and 7). Patients can experience chest pain either during or after endomyocardial biopsy (Ref. 7). The most frequently occurring hazard reported in the literature is ectopy (a heartbeat originating from a location in the heart other than the normal originating location) (Refs. 1 through 8). Preventricular contractions (PVC's) occur when the forceps engage the myocardial wall. The PVC's are usually isolated, but runs of PVC's and even sustained ventricular tachycardias (extremely rapid heart rates) requiring cardioversion (electrical shock used to return the heart to its normal rhythm) have been reported (Refs. 7 and 8). Temporary right bundle branch block of 5 minutes duration has been reported in dogs (Ref. 8). It appears that biopsy of the right ventricle is associated with more complications and a higher failure rate than is biopsy of the left ventricle (Ref. 7). Although hazards associated with use of this device are numerous and can be serious or even fatal, they do not appear to be frequent. One study of 164 patients (more than 1,000 biopsy procedures) revealed a low incidence of complications in both ventricles (Ref. 7, table IV). A Stanford University study involving over 600 biopsy procedures demonstrated no significant morbidity and no mortality associated with the use of the endomyocardial biopsy device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Improper mechanical design can cause premature release of a biopsy specimen that then becomes an embolus. (c) Damage to heart tissue: Endomyocardial hemorrhage, perforation of the heart, and cardiac arrhythmias can all result from improper mechanical design.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the endomyocardial biopsy device be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance. Although endomyocardial biopsy devices are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Sakakibara, S. and S. Konno, "Endomyocardial Biopsy," *Japanese Heart Journal* 3(6):537-543, November 1962.

2. Ali, N., "Transvenous Endomyocardial Biopsy Using the Gastrointestinal Biopsy (Olympus GFB) Catheter," *American Heart Journal* 87(3):194-197, March 1974.

3. Caves, P. K. and W. P. Schulz, et al., "New Instrument For Transvenous Cardiac Biopsy," *American Journal of Cardiology*, 33:264-267, February 1974.

4. Richarson, P. J., "King's Endomyocardial Bioptome," *Lancet*, 660-661, April 1974.

5. Dawai, C. and Y. Kitaura, "New Endomyocardial Biopsy Catheter for the Left Ventricle," *American Journal of Cardiology*, 40:63-65, July 1977.

6. Blaufuss, A. and D. Garner, et al., "Technique for Serial Right and Left Ventricular Endomyocardial Biopsy in Dogs" *Journal of Applied Physiology*, 40(5):832-835, May 1976.

7. Brooksy, I. A. and B. S. Jenkins, et al., "Left Ventricular Endomyocardial Biopsy. I: Description and Evaluation of the Technique," *Catheterization and Cardiovascular Diagnosis* 3(2):115-121, 1977.

8. Hirota, Y. L., F. Khaja, and W. H. Abelmann, "Effectiveness and Hazard of Endomyocardial Biopsy in Dogs: Comparison of Two Methods," *American Heart Journal*, (92)6:767-772, Dec. 1976.

9. Copeland, J. G. and E. B. Stinson, et al., "Cardiac Transplantation at Stanford," *Acta Chirurgica Belgium* 76(3):387-392, May-June 1977.

10. Mackay, E. H., D. Pickering, and W. A. Littler, "Cardiac Biopsy in Childhood," *Archives of Disease in Children*, 52(10):785-789, October 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513,

701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 by adding Subpart E and new § 870.4075 as follows:

Subpart E—Cardiovascular Surgical Devices

§ 870.4075 Endomyocardial biopsy device.

(a) *Identification.* An endomyocardial biopsy device is a device used to remove samples of tissue from the inner wall of the heart.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFC-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6249 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1509]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Accessory Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass accessory equipment into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypas accessory equipment:

1. Identification: Cardiopulmonary bypass accessory equipment is equipment that includes devices having no contact with blood-material that are used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system priming equipment.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass accessory equipment be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This equipment plays an important role in the setup and function of the cardiopulmonary bypass circuit. Failure of the equipment to perform its intended purpose could lead to serious hazards such as cessation of perfusion (passage of fluid through the vessels of an organ) or cessation of oxygenation (oxygen uptake by the blood). Performance characteristics should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, or maintained. This equipment does not include any devices that have been classified individually as items of cardiopulmonary bypass equipment under other regulations in this section. The Panel believes that general controls alone would not provide sufficient control over the performance characteristcs of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cessation of perfusion: Failure of the device due to poor mechanical design can require temporary cessation of the perfusion. (b) Cessation of oxygenation: Failure of the device due to poor mechanical design can require temporary cessation of oxygenation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass accessory equipment be classified into class II (performance standards.) The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4200 as follows:

§ 870.4200 Cardiopulmonary bypass accessory equipment.

(a) *Identification.* Cardiopulmonary bypass accessory equipment is equipment that includes devices having no contact with blood-material that are used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing

Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6250 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1378]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Bubble Detectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass bubble detectors into class II (performance standards). The FDA is also publishing the recommendation of the cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering the public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass bubble detectors:

1. Identification: A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass bubble detector be classified into class II because this device is neither life-sustaining but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise detection of gaseous emboli, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to detect bubbles, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device releases an acceptable energy level into the bloodstream when functioning normally. If the device malfunctions, however, unsafe energy levels may be released, especially if the device utilizes ultrasound techniques. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue and blood damage: If not properly designed, devices that release ultrasonic energy into the body can release such energy at levels which may damage tissue and blood. (b) Gas embolism: Failure of the device to detect gas emboli in the extracorporeal circuit can allow potentially debilitating or fatal gas emboli to enter the patient's circulation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the cardiopulmonary bypass bubble detector be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4205 as follows:

§ 870.4205 Cardiopulmonary bypass bubble detector.

(a) *Identification.* A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6248 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1510]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Vascular Catheters, Cannulas, and Tubing

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass vascular catheters, cannulas, and tubing into class II. The effect of classifying a device into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the devices be classified into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1977. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food And Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass vascular catheters, cannulas, and tubing:

1. Identification: Cardiopulmonary bypass catheters, cannulas, and tubing are devices used in cardiopulmonary bypass surgery to cannulate the vessels, perfuse the coronary arteries, and interconnect the catheters and cannulas with an oxygenator and the accessory bypass equipment.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a medium priority. 3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass vascular catheters, cannulas, and tubing be classified into Class II because these devices are neither life-supporting nor life-sustaining, but are potentially hazardous to life or health even when properly used. Because the devices are placed directly in contact with the bloodstream, they should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the devices should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The devices should be mechanically designed to minimize blood trauma and to prevent leakage. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of these devices. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard to provide such assurance. 4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the devices and on their personal knowledge of, and experience with, the devices. 5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in these devices and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Tissue and blood damage: If the materials, surface finish, or cleanliness of these devices are inadequate, damage to the blood and tissue may result. (c) Loss of blood: Lack of integrity of the connections between these devices and adapters and connectors used to join these devices together causes blood leakage.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that cardiopulmonary bypass vascular catheters, cannulas, and tubing be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in subpart E by adding new § 870.4210 as follows:

§ 870.4210 Cardiopulmonary bypass vascular catheters, cannulas, and tubing.

(a) *Identification.* Cardiopulmonary bypass catheters, cannulas, and tubing are devices used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and interconnect the catheters and cannulas with an oxygenator, and the accessory bypass equipment.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs

[FR Doc. 79-6251 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1511]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Heart-Lung Machine Consoles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass heart-lung machine consoles into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classi-

fied into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20587.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA Advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass heart-lung machine consoles:

1. Identification: A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass heart-lung machine console be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. The device is electrically powered and presents a potential hazard to the patient either by power failure or electrical leakage current. Thus, the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient informaton to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias of electrical shock: Excessive electrical leakage current can distrub the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician, during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Failure to provide sufficient power to the life-support equipment: If the device cannot operate within the expected range of line voltage, it may fail to provide sufficient power to the cardiopulmonary bypass circuit and cause the circuit to cease working.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass heart-lung machine console be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4220 as follows:

§ 870.4220 Cardiopulmonary bypass heart-lung machine console.

(a) *Identification.* A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 6252 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1512]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Defoamers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass defoamers into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass defoamers:

1. Identification: A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardivascular bypass surgery to remove gas bubbles from the blood.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass defoamer be classified into class III because, although this device is neither life-supporting nor life-sustaining, it presents a potential unreasonable risk of illness or injury. Failure of the device to adequately remove gas bubbles from the blood in the extracorporal circuit can lead to substantial hazards to the patient's life or health. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. The materials used in the device should demonstrate minimal tendency to embolize and adequate ability to remove bubbles. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is insufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood may result. (b) Gas embolism: Inability of the device to adequately remove gas bubbles from the blood can allow potentially debilitating or fatal gas emboli to escape into the bloodstream.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass defoamer classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use in removing gas bubbles from the blood in the cardiopulmanary bypass circuit which is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because if the device fails to remove gas bubbles from the blood, a potentially debilitating or fatal gas embolism could result. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4230 as follows:

§ 870.4230 Cardiopulmonary bypass defoamer.

(a) *Identification.* A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiovascular bypass surgery to remove gas bubbles from the blood.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6253 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1513]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Heat Exchangers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass heat exchangers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass heat exchangers:

1. Identification: A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system, used in extracorporeal circulation to warm or cool the blood or profusion fluid flowing through the device.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass heat exchanger be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. The device is attached to the body through an extracorporeal blood circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus if the device is electrically powered, the electrical characteristics of the device, e.g., electrical leakage current, need to meet certain requirements. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. When the device transfers heat between one fluid and the blood, integrity of the separation of the two fluids must be maintained. The device should protect against the release of unsafe energy levels into the blood. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's heat transfer characteristics, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: If the device is electrically powered, excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Blood loss or contamination: The integrity of the fluid channels must be maintained to prevent leakage between the blood and water sides of the device causing either loss of blood into the water or contamination of the blood by the water. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (d) Blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood may result. Also, excessive or uncontrolled heat transfer due to physical properities of the materials used in the device or to a mismatch of the heat exchanger and temperature controller can cause blood damage. (e) Infection: Sterility of the device must be ensured to prevent infection.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass heat exchanger be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4240 as follows:

§ 870.4240 Cardiopulmonary bypass heat exchanger.

(a) *Identification.* A cardiopulmonary bypass heat exchanger in a device, consisting of a heat exchange system, used in extracorporeal circulation to warm or cool the blood or profusion fluid flowing through the device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6254 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1514]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Temperature Controllers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass temperature controllers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the de-

velopment of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass temperature controllers:

1. Identification: A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass temperature controller be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the cardiopulmonary bypass circuit through the heat exchanger and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to control temperature should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Blood damage or thermal complications: Inaccuracy or instability of temperature control can lead to blood damage or thermal complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass temperature controller be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4250 as follows:

§ 870.4250 Cardiopulmonary bypass temperature controller.

(a) *Identification.* A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.

(b) *Classification.* Class II (performamce standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6255 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1515]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Arterial Line Blood Filters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass arterial line blood filters into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comment by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass arterial line blood filters:

1. Identification: A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or

pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass arterial line blood filter be classified into class III because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used, and because there are insufficient data to establish the safety and effectiveness of the device. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's filtration efficiency, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that there is insufficient medical and scientific data on which to base a performance standard for this device. The Panel also believes that the test methodology for establishing satisfactory performance levels is not available. In addition, it has not been clearly established that adverse physiological effects follow when this device is absent from the circuit. Because insufficient information exists to establish a performance standard to provide reasonable assurance of the device's safety and effectiveness, the Panel believes that this device requires premarket approval.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inderent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel reviewed the relevant medical literature. References were supplied to the Panel by Panel member Dr. Richard E. Clark, FDA, and Pall Biomedical Products Corp. The summaries from FDA and Pall Biomedical are attached as addenda to the April 4, 1977, minutes of the Cardiovascular Device Classification Panel meeting. Dr. Clark's memorandum is an addendum to the May 2, 1977, minutes of the Cardiovascular Device Classification Panel meeting. Dr. Clark's report (Ref. 1) states that arterial line filters require more complex testing and safety considerations than other blood filters because of their use in a perfusion line which is life-supporting.

Three general problems arise with the use of arterial line filters: excessive pressure gradient or inadequate flow, thromboembolic complications, and embolic complications. Excessive pressure gradients or inadequate flow are caused by blockage of the filter during use. This problem has been handled clinically in two ways: (1) two parallel filters operate simultaneously, alternately, or alternately only when transfilter ' pressure differences become large; (2) one filter is used with a bypass line. It is important that the capacity of arterial line filters be sufficient to provide adequate blood flow throughout the course of cardiopulmonary bypass surgery. Depth filters may start to channel after 30 to 40 percent of the void spaces are filled, thus lowering efficiency and providing a possible escape for larger micro particles (Ref. 1).

Thromboembolic complications are not well documented in the literature. Blood filters cause a reduction in platelet count, but investigations have shown that the platelets retained by a filter are usually nonfunctioning (Ref. 2). Because of this fact, the impairment of platelet function is not nearly as great as the decrease in the number of platelets would appear to suggest.

The third problem with arterial line filters is embolic complications. Small microemboli have been confirmed to be a cause of detrimental alterations in pulmonary physiology (Refs. 3 through 6). Dr. Clark (Ref. 1) summarizes the problem as follows: "A second major consideration is that of high removal of gaseous microemboli. Although oxygen and carbon dioxide are the two gases used during extracorporeal circulation, the untoward effects of small (less than 20 to 30 micron) microbubbles have not been documented to date for two reasons. First, it is very difficult to generate uniform size bubbles in the size range of 25 to 50 microns, and the bubble size may not remain constant in a non-Newtonian turbulent flow field. Second, no highly accurate on-line, continuous noninvasive system for measurement of size and total particles per unit time has appeared. Consequently, the total number by size and the distribution of types of microemboli in the arterial line, i.e., gas, protein solids, and nonprotein solids, have not been ascertained. In summary, the pathophysiologic data and the means by which to obtain that data are still lacking."

Most investigators state that blood filters are invaluable for removing harmful aggregates induced by extracorporeal circulation (Refs. 2 and 6 through 10). However, adequate filter capacity and effective filtration are important for this application, as obstruction could be a serious hazard to the patient. Although fresh in vivo blood has very few of the filterable elements per unit (500 milliliters), the high flow rate in an arterial line (3 to 5 liters per minute) and its pulsing can cause problems due to excessive turbulence and high frequency vibration in the filter (Ref. 8). This can cause platelet and fibrin destruction resulting in a clogged filter just when an adequate flow of blood is needed the most (Refs. 6 and 8). Arterial circuit application requires a special design to reduce turbulence and a greatly increased capacity to handle the added flow rate and time needed for an operation. Filters on the market as of 1975 seem to do a good job for short periods of time (less that 4 hours) on dogs weighing 20 to 30 kilograms (Ref. 9). However, Heimbecker's studies (Ref. 8) indicate that line filters experiencing blood flows of 3 to 5 liters per minute that are not designed for such flows may actually generate fibrin emboli, which are released into the systemic circulation causing neurologic, pulmonary, and renal complications. From this data and their experience, the Panel concluded that there do not exist sufficient safety and effectiveness data on which adequate performance standards could be based.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Inadequate blood flow: Inadequate capacity of the device to filter the amount of blood flowing through it during a cardiopulmonary bypass operation could lead to inadequate flow or excessive pressure gradient. (c) Embolic complications: Inability of the device to properly filter particles can lead to embolic complications. (d) Gas embolism: Inability of the device to properly filter microbubbles from the extracorporeal circulation is associated with gas embolism.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass arterial line blood filter be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use in removing emboli from the blood in the cardiopulmonary bypass circuit which is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because if the device fails to remove emboli from the blood, a potentially debilitating or fatal embolism may result. The Commissioner believes that insufficient information exists to determine that general controls will

provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Memorandum to the Cardiovascular Device Classification Panel from Richard E. Clark, M.D., minutes of the May 2, 1977 meeting.

2. Lindsay, R., C. Forbes, C. Thompson, and C. Prentice, "The Effect of Blood Filtration on Platelets," *British Journal of Hacmatology*, 28(1):146, 1974.

3. Barrett, J., E. Miller, and M. Litwin, "Filtration Characteristics of Polyester Mesh (Pall) Micropore Blood Transfusion Filter," *Surgery*, 111(1):56-59, 1976.

4. Barrett, J., H. Dhurandhar, E. Miller, and M. Litwin, "Comparison in Vivo of Dacron Woll (Seank) and Polyester Mesh (Pall) Micropore Blood Transfusion Filters in the Prevention of Pulmonary Microembolism Associated with Massive Transfusion," *Annals of Surgery*, 182(6):690-695, 1975.

5. Connell, R. and M. Webb, "Filtration Characteristics of Three New In-Line Blood Transfusion Filters," *Annals of Surgery*, 181(3):273-278, 1975.

6. Cullen, D. and L. Ferrara, "Comparative Evaluation of Blood Filters: A Study in Vitro," *Anesthesiology*, 41:568, 1974.

7. Mason, K., L. Hall, R. Lamoy, and C. Wright, "Evaluation of Blood Filters: Dynamics of Platelets and Platelet Aggregates," *Surgery*, 77(2):235-240, 1975.

8. Heimbecker, R., C. Robert, and F. McKenzie, "The Extracorporeal Pump Filter—Saint or Sinner?", *Annals of Thoracic Surgery*, 21:55, 1976.

9. Guidoin, R., Y. Laperche, J. Awad, and J. Winchester, "Disposable Filters for Microaggregate Removal from Extracorporeal Circulation," *Journal of Thoracic and Cardiovascular Surgery*, 71:502, 1976.

10. Carlson, R. G., "Lande-Edwards Membrane Oxygenator For Heart Surgery and Prolonged Lung or Heart Support," *New York State Journal of Medicine*, 2353, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4260 as follows:

§ 870.4260 Cardiopulmonary bypass arterial line blood filter.

(a) *Identification.* A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6256 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1516]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass cardiotomy suction in line blood filters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of cardiopulmonary bypass cardiotomy suction line blood filters:

1. Identification: A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass cardiotomy suction line blood filter be classified into class II because the device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health if it fails to filter the blood effectively. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's filtration efficiency, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that performance standards will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the

device. In addition, the Panel found further evidence for their recommendation in the medical literature. Literature was supplied to the Panel by Panel member Dr. Richard E. Clark, FDA, and Pall Biomedical Products Corp. The statements submitted by FDA and Pall Biomedical are attached as addenda to the April 4, 1977 minutes of the Cardiovascular Device Classification Panel meeting. Dr. Clark's review is provided as an addendum to the May 2, 1977 minutes of the Cardiovascular Device Classification Panel meeting. The literature on cardiotomy line filters indicates that problems arising during clinical perfusions in which the device is used are usually not life threatening. The blood filtered by this device is removed from the operative field by suction, and contains a large amount of fat and debris and has a large blood gas interface (Ref. 1). Gaseous emboli present no problem in the use of this filter, nor do excessive pressure gradients, because only a small percentage of the total blood pumped passes through the cardiotomy filter system. The particle size range estimated to be of importance is probably greater than 20 to 25 microns (Ref. 2). Several referenced reports note certain advantages of filtering blood during infusions, including decrease in oxygen consumption with the use of filtered blood (Ref. 3). Infusion filters have also been found to keep the lungs free of emobli (Ref. 4). The incidence of pulmonary insufficiency in trauma patients was lower when filtered blood was used. (Ref. 5). Studies have shown that blood microfilters accumulate twice as much debris as standard 170-micron infusion set filters (Ref. 6). Reports have also shown that these migrating thrombi, which would be filtered by this device, are associated with neuro-ophthalmic disturbances (Ref. 7), convulsive episodes (Ref. 8), and other cerebral and pulmonary complications (Refs. 6, 9, 10, 11, and 12). While a filter with small pore sizes is a more effective filter, the pores tend to clog easily and thus reduce the filter's capacity. Although it is possible to design a filter with larger pores that could operate for an hour without obstruction, such a filter would miss many potentially harmful microaggregates. (Refs. 10, 11, 12, and 13). Filters with large pores also tend to leak aggregates because of pressure extrusion of some particles occluding the pores of the filter (Refs. 10, 11, and 12). Filters currently on the market compromise either capacity or smaller pore size. In the Panel's opinion, for the limited volume of cardipulmonary bypass cardiotomy suction line blood filters handled by the cardiotomy line filter, sufficient filtration efficiency and capacity will be assured through performance standards.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli. (b) Particle embolism: Inability of the device of filter properly particles from the blood can lead to potentially debilitating or fatal emboli.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass cardiotomy suction line blood filter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Clark, R. E., and H. W. Margraf, "Fat and Solid Filtration in Clinical Perfusions," *Surgery*, 77:216-224, 1975.

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4. Guidoin, R., Y. Laperche, L. Martin, and J. Awad, "Disposable Filters for Microaggregate Removal From Extracorporeal Circulation," *Journal of Thoracic and Cardiovascular Surgery*, 71:504, 1976.

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12. Connell, R., and M. Webb, "Filtration Characteristics of Three New In-Line Blood Transfusion Filters," *Annals of Surgery*, 181(3):273-278, 1975.

13. Gervin, A., K. Mason, and C. Wright, "The Filtration Limitations of Ultrapore Filters," *Surgery*, 7(92):186-193, 1975.

14. "Blood Transfusion Micro-filter Standard," Association for the Advancement of Medical Instrumentation, Arlington, Va., 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4270 as follows:

§ 870.4270 Cardiopulmonary bypass cardiotomy suction line blood filter.

(a) *Identification.* A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.

(b) *Classification.* Class II (performance standards).

Intersted persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6257 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1517]

MEDICAL DEVICES

Classification of Cardiopulmonary Prebypass Filters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary prebypass filters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary prebypass filters:

1. Identification: A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not to be used to filter blood.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary prebypass filter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to filter particulates from the system during priming, those particles can be introduced into the body during the subsequent perfusion. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to filter particles, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Infusion of foreign particulates: Inadequate design of the filter can lead to unnecessary infusion of foreign particles into the patient which may lead to post bypass neural, renal, or pulmonary complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary prebypass filter by classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4280 as follows:

§ 870.4280 Cardiopulmonary prebypass filter.

(a) *Identification.* A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not to be used to filter blood.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6258 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1518]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Adaptors, Stopcocks, manifolds, and fittings

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that these devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30

days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of THE FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings:

1. Identification: Cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings are devices used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings be classified into class II because the devices are neither life supporting nor life sustaining but are potentially hazardous to life or health even when properly used. Because the devices are placed directly in contact with the bloodstream they should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the devices should meet a generally accepted satisfactory level of blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of these devices. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the devices and on their personal knowledge of, and experience with, the devices.

5. Risks to health: (a) Thromboembolism: inadequate blood compatibility of the materials used in these devices and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Blood damage: If the materials, surface finish, or cleanliness of these devices are inadequate, damage to the blood may result. (c) Blood or infusion fluid loss: Improper mechanical design of the devices can lead to blood or infusion fluid leakage. (d) Infection: Sterility of the device must be ensured to prevent infection.

PROPOSED CLASSIFICATION

The commissioner agrees with the Panel's recommendation and is proposing that cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4290 as follows:

§ 870.4290 Cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings.

(a) *Identification.* Cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings are devices used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6259 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1519]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Gas Control Units

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass gas control units into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification

of cardiopulmonary bypass gas control units.

1. Identification: A cardiopulmonary bypass gas control unit is a device used to control and measure the flow of gas into the oxygenator. The device is calibrated for a specific gas.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass gas control units be classified into class II because the device is neither life-sustaining nor life-supporting, but improper gas flow rates allowed by the device are potentially hazardous to life and health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's flow control, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Inadequate gas transfer: Inaccuracy or instability of the flow control can lead to inadequate or excessive gas transfer.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass gas control unit be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4300 as follows:

§ 870.4300 Cardiopulmonary bypass gas control unit.

(a) *Identification.* A cardiopulmonary bypass gas control unit is a device used to control and measure the flow of gas into the oxygenator. The device is calibrated for a specific gas.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6260 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1520]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Coronary Pressure Gauges

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass coronary pressure gauges into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass coronary pressure gauges:

1. Identification: A cardiopulmonary bypass coronary pressure gauge is a device used in cardiovascular bypass surgery to measure the pressure of the blood perfusing the coronary arteries.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass coronary pressure gauge be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of the pressure in the coronary artery perfusion line, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. This device is attached to the body through the extracorporeal blood circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is

sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Inadequate or excessive blood supply to the coronary arteries: If the zero or calibration of the device is inaccurate or unstable, the device may generate false pressure readings. If false pressure readings are used in managing the patient, inadequate or excessive blood may be supplied to the coronary arteries.

(b) Cardiac arrhythmias or electrical shock: If the device is electrically powered, excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass coronary pressure gauge be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4310 as follows:

§ 870.4310 Cardiopulmonary bypass coronary pressure gauge.

(a) *Identification.* A cardiopulmonary bypass coronary pressure gauge is a device used in cardiovascular bypass surgery to measure the pressure of the blood perfusing the coronary arteries.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6261 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1521]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Pulsatile Flow Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass pulsatile flow generators into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass pulsatile flow generators:

1. Identification: A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.

2. Recommended classification: class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass pulsatile flow generator be classified into class III because, although this device is neither life-supporting nor life-sustaining, it is potentially hazardous to life or health even when properly used, and because there are insufficient data to establish the safety and effectiveness of this device. This device is attached to the body through the blood and the extracorporeal oxygenator circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Although the device releases an acceptable energy level into the bloodstream when functioning properly, unsafe energy levels may be released if the device malfunctions. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to provide pulsatile flow, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. In addition, the performance characteristics of the device are not well-defined and the data on them are insufficient to establish a performance standard. The Panel believes that premarket approval is necessary to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated

with the inherent properties of the device and on their personal knowledge of, and experience with, the device. The Panel believes that data do not exist to demonstrate the safety and efficacy of the device and that clinical trials are currently the only method capable of establishing safety and efficacy.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physican during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Blood damage: If the materials, surface finish, cleanliness, or mechancial design of this device are inadequate, damage to the blood may result. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device, inadequate surface finish and cleanliness, or improper mechanical design may lead to potentially debilitating or fatal thromboemboli. (d) Gas embolism: Rupture of the pumping bladder or a leak in the pumping chamber can allow potentially debilitating or fatal gas emboli to escape into the bloodstream.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass pulsatile flow generator be classified into class III (premarket approval). After reviewing the literature, FDA has found that pulsatile flow in oxygenator circuits is a major topic of debate. The hazards of pulseless flow of a rate less than 100 milliliters per kilogram per minute have been listed as metabolic acidosis, weight gain, edema, visceral pooling, capillary stasis, opening of the arterial venous shunt, and decreased lymph flow (Ref. 1). However, at greater flow rates it is stated that none of these changes is apparent and no significant physiological differences occur. Increased renin production has also been shown to occur with pulseless flow (Refs. 2 and 3), and it has been hypothesized that reduced reticuloendothelial system phagocytic function (white blood cell defensive function can occur due to prolonged pulseless flow (Ref. 4). On the other hand, pulsatile flow has been indicated in increased blood damage and a greater chance of rupture or leaks in the extracorporeal circuit (Refs. 2 and 5). The data to support either side of this controversy are not convincing. The Commissioner believes the device is purported or represented to be for a use in establishment of pulsatile flow through the cardiopulmonary bypass circuit which may be of substantial importance in preventing impairment of human health. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Nose, Y., "The Oxygenator," *in* "Manual and Artificial Organs," Vol. 2., C. V. Mosby, St Louis, pp. 167-175, 1973.

2. Bartlett, R. H. and B. E. Harken, "Instrumentation for Cardiopulmonary Bypass: Present and Future," *Medical Instrumentation*, 10(2):119-124, 1976.

3. Many, M. et al., "Effects of Depulsation of Renal Blood Flow Upon Renal Function and Renin Secretion," *Surgery*, 66(1):242-249, 1969.

4. Kusserow, D. K., R. W. Laro, and J. E. Nickels, "Decreased Reticuloendothelial Phagocytic Function Following Prolonged IN VIVO Blood Pumping—Preliminary Observations," *in* "Transactions of the American Society for Artificial Internal Organs," 21:388-393, 1975.

5. Bartlett, R. H., "Mechancial Cardiopulmonary Substitution During Open-Heart Surgery," *Cardiovascular Clinics*, 3(3):134-152, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat, 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposed to amend Part 870 in Subpart E by adding new § 870.4320 as follows:

§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.

(a) *Identification.* A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.

(b) *Classification.* Class III (premerket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in bracket in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6263 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1522]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass On-Line Blood Gas Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass on-line blood gas monitors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Admendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification

of cardiopulmonary bypass on-line blood gas monitors:

1. Identification: A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.

2. Recommended clasification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass on-line blood gas monitors be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the cardiopulmonary bypass circuit through a transducer and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood gas levels, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass on-line blood gas monitor be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4330 as follows:

§ 870.4330 Cardiopulmonary bypass on-line blood gas monitor.

(a) *Identification.* A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6264 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1523]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Level sensing Monitors and/or Controls

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass level sensing monitors and/or controls into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

Dates: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass level sensing monitors and/or controls:

1. Identification: A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass level sensing monitor and/or control be classified into class II because the device is neither life-supporting nor

life-sustaining, but loss of reservoir volume undetected and/or uncontrolled by the device is potentially hazardous to life and health. This device is attached to the cardiopulmonary bypass circuit through a transducer and is used in a clinical environmemt where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's sensing and measurement of the blood level in the reservoir, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Introduction of air into the extracorporeal blood circuit: If the sensing circuit or alarm is inaccurate or unreliable, the level of blood in the resevoir could fall to zero and allow air to enter the extracorporeal blood circuit.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass level sensing monitor and/or control be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4340 as follows:

§ 870.4340 Cardiopulmonary bypass level sensing monitor and/or control.

(a) *Identification.* A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food, and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6265 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1524]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Oxygenators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the cardiopulmonary bypass oxygenator into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass oxygenators:

1. Identification: A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass oxygenator be classified into class III because this device is life-supporting and presents a potential unreasonable risk of illness or injury. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to exchange gas, and to minimize blood damage and particulate generation, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believe that general controls alone

would not provide sufficient control over the performance characteristics of this device. The Panel members also believes that insufficient medical data exist concerning the performance and design characteristics of the device to establish a performance standard to provide reasonable assurance of the device's safety and effectiveness. Therefore, the Panel believes that this device needs to be subject to premarket approval.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, their personal knowledge of, and experience with, the device, and the lack of sufficient scientific and medical data to enable the development of performance standards to assure the safety and effectiveness of the device.

5. Risks to health: (a) Blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood may result. (b) Inadequate or excessive gas transfer: Improper design of the gas transfer mechanism can lead to this hazard. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (d) Gas embolism: Inadequate debubbling, filtering, or separation of the gas and blood phases can lead to potentially debilitating or fatal gas embolism.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass oxygenator be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (providing oxygen and carbon dioxide transfer for the blood during cardiopulmonary bypass operations) in supporting or sustaining human health. The act requires the Commissioner to classify a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4350 as follows:

§ 870.4350 Cardiopulmonary bypass oxygenator.

(a) *Identification.* A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner
Regulatory Affairs.

[FR Doc. 79-6266 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1525]

MEDICAL DEVICES

Classification of Nonroller-Type Cardiopulmonary Bypass Blood Pumps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonroller-type cardiopulmonary bypass blood pumps into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonroller-type cardiopulmonary bypass blood pumps:

1. Identification: A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the nonroller-type cardiopulmonary bypass blood pump be classified into class III because this device is life supporting and life sustaining and is potentially hazardous to life or health even when properly used. This device is attached directly to the cardiopulmonary bypass circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, or maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel reviewed the medical literature. At present, there are several types of blood pumps available. These types can be divided into two categories: pulsatile flow pumps and nonpulsatile flow pumps. Pulsatile pumps are of a diaphragmatic, pneumatic, piston, bellows, or bar compression design (Ref. 1). There are three main issues concerning blood pumps that are addressed in the literature: (1) the advantages and disadvantages of pulsatile flow (Refs. 1 through 3 and 5 through 12), (2) the effect of occlusive versus nonocclusive roller pressure (Refs. 1 through 4), and (3) the effect on the patient of particulate, including any developed by the pump, from the extracorporeal circuit (Refs. 13 through 17). The controversy over pulsatile flow is a major topic of debate in the literature. Nose (Ref. 1) listed the hazards of pulseless flow of a rate less than 100 milliliters per kilogram per minute as metabolic acidosis, weight gain, edema, splanchnic pooling, capillary stasis, opening of the arterial venous shunt, and decreased lymph flow. However, at greater flow rates it is stated that none of these changes are apparent and no significant physiological differences occur. Increased renin production has also been shown to occur with pulseless flow (Refs. 2 and 5), and Kusserow et al. (Ref. 6) have hypothesized that reduced reticuloendothelial system phagocytic function (white blood cell defensive function) can occur due to prolonged pulseless flow. Bartlett (Refs. 2 and 3) indicates that many of the problems of pulseless flow can be controlled and that, because of pulsatile flow through narrow cannula, blood velocity increases causing increased hemolysis and a greater chance of rupture or leaks. Therefore, he believes a roller pump to be the equipment of choice. However, many authors (Refs. 5 through 12) disagree with this position and favor pulsatile flow. It does not appear that this conflict will be resolved easily or in the near future. From the literature reviewed, the Panel believes that sufficient data do not exist to establish adequate performance standards to assure the safety and effectiveness of nonroller-type cardiopulmonary bypass blood pumps.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electric leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood may result. Improper mechanical design of the device can also lead to this hazard. (c) Variability in stroke volume: The design of the pump head and the torque developed by the pump are characteristics of the device that can lead to variability in stroke volume. (d) Embolism: Improper design of the device may cause the generation of gaseous, particulate,, or thrombotic embolisms, which may be debilitating or fatal.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that nonroller-type cardiopulmonary bypass blood pumps be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (pumping the blood through the cardiopulmonary bypass circuit) in supporting or sustaining human health. The act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectivness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) any may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Nosé, Y., "The Oxygenator," *in* "Manual on Artificial Organs," Vol. 2, C. V. Mosby Co., St. Louis, pp. 167-175, 1973.

2. Bartlett, R. H. and D. E. Harken, "Instrumentation for Cardiopulmonary Bypass—Past, Present and Future," *Medical Instrumentation*, 10(2):119-124, 1976.

3. Bartlett, R. H., "Mechanical Cardiopulmonary Substitution During Open Heart Surger," *Cardiovascular Clinics*, 3(3):134-152, 1971.

4. Bernstein, E. F. and L. R. Gleason, "Factors Influencing Hemolysis with Roller Pumps," *Surgery*, 61(1):432-442, 1967.

5. Many, M., F. Giron, W. C. Birtwell, R. A. Deterling, and H. S. Saroff, "Effects of Depulsation of Renal Blood Flow Upon Renal Function and Renin Secretion," *Surgery*, 6(1)A242-249, 1969.

6. Kusserow, B. K., R. W. Larrow, and J. E. Nichols, "Decreased Reticuloendothelial Phagocytic Function Following Prolonged IN VIVO Blood Pumping—Preliminary Observations," *Transactions of the American Society for Artificial Internal Organs*, 21:388-393, 1975.

7. Jacobs, L. A., W. Seamone, and V. L. Gott, "Improved Organ Function During Cardiac Bypass with a Roller Pump Modified to Deliver Pulsatile Flow," *Journal of Thoracic and Cardiovascular Surgery*, 58(5):704-712, 1969.

8. Dalton, M. L., R. T. McCarty, K. E. Woodward, and T. G. Barila, "The Army Artificial Heart Pump. II. Comparison of Pulsatile and Nonpulsatile Flow," *Surgery*, 58(5):840-845, 1965.

9. Trinkle, J. K., N. E. Helton, R. E. Wood, and L. R. Bryant, "Metabolic Comparison of a New Pulsatile Pump and a Roller Pump for Cardiopulmonary Bypass," *Journal of Thoracic and Cardiovascular Surgery*, 58(4):562-569, 1969.

10. Sallam, I. A., A. Shaw, and W. H. Bain, "Experience in the Development of Low Haemolysis Pumps," *Physics in Medicine and Biology*, 21(2):272-279, 1976.

11. Sanderson, J. M., P. G. Morton, T. S. Tolloczki, T. Vennart, and G. Wright, "The Morton-Keele Pump—A Hydraulically Activated Pulsatile Pump for Use in Extracorporeal Circulation," *Medical and Biological Engineering*, 11(2):182-190, 1973.

12. Balakrishnan, S. and D. Sridhar, "Development of a Pulsatile Blood Pump," *Biomaterials, Medical Devices, Artificial Organs*, 4(3-4):323-332, 1976.

13. Ashmore, P. G., V. Svitek, and P. Ambrose, "The Incidence and Effects of Particulate Aggregation and Microembolism in Pump-Oxygenator Systems," *Journal of Thoracic and Cardiovascular Surgery*, 55(5):691-697, 1968.

14. Kessler, J. and R. H. Patterson, "The Production of Microemboli by Various Blood Oxygenators," *Annals of Thoracic Surgery*, 9(3):221-228, 1970.

15. Patterson, R. H. and J. Kessler, "Microemboli during Cardiopulmonary Bypass Detected by Ultrasound," *Surgery, Gynecology and Obstetrics*, 129:505-510, 1969.

16. Simmons, E., E. Litchi, S. Dwyer, B. Rowley, R. Young, J. Mackenzie, and C. H. Almond, "Detection of Microparticles During Cardiopulmonary Bypass by Use of Electronic Devices," *in* "Mechanical Devices for Cardiopulmonary Assistance," *Advances in Cardiology*, 6:94-110, 1971.

17. "Safety and Efficacy of Blood Oxygenators," FDA contract No. 223-74-5253, Utah Biomedical Test Laboratory, Final report, May 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4360 as follows:

§ 870.4360 Nonroller-type cardiopulmonary bypass blood pump.

(a) *Identification.* A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump the

blood through the cardiopulmonary bypass circuit during bypass surgery

(b) *Classification.* Class III (premarket approval).

Interested pesons may, on or before May 3, 1979 , submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6267 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1526]

MEDICAL DEVICES

Classification of Roller-Type Cardiopulmonary Bypass Blood Pumps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying roller-type cardiopulmonary bypass blood pumps into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-350), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of roller-type cardiopulmonary bypass blood pumps:

1. Identification: A roller-type cardiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: Although this device is life-supporting, the Panel recommends that the cardiopulmonary bypass roller-type blood pump be classified into class II. This electrically powered device pumps the blood through the extracorporeal blood circuit, is directly attached to the cardiopulmonary bypass circuit, and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to pump the blood, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel reviewed the medical literature concerning this device and found further support for their recommendation. At present, there are several types of blood pumps available. These can be divided into two categories, namely, pulsatile flow pumps and nonpulsatile flow pumps. The roller pump is an example of a nonpulsatile type of pump. It is the most commonly used pump for cardiopulmonary bypass because it is reliable, durable, and easy to regulate and operate (Ref. 3). There are three main issues concerning blood pumps that are addressed in the literature: (1) the advantages and disadvantages of pulsatile flow (Refs. 1 through 3, and 5 through 12), (2) the effect of occlusive versus nonocclusive roller pressure (Refs. 1 through 4), and (3) the effect on the patient of particulates, including any developed by the blood pump, from the extracorporeal circuit (Refs. 13 through 17). Bartlett (Refs. 2 and 3) indicates that many of the problems of pulseless flow can be controlled and that, because of pulsatile flow through narrow cannula, blood velocity increases causing increased hemolysis and a greater chance of rupture of leaks. Therefore, Bartlett believes a roller pump to be the preferable choice. The literature indicates concern over blood damage caused during compression of the pump tubing by the rollers. Hemolysis was the main problem addressed in this regard. Nosé (Ref. 1) states that hemolysis increases directly with the number of rollers on the pump and the occlusive pressure applied by these rollers. This is supported by Bernstein and Gleason (Ref. 4). However, Bartlett (Ref. 2) indicates no difference in hemolysis between "almost" occlusive and completely occlusive pressure settings. Nosé (Ref. 1) and Bernstein and Gleason (Ref. 4) mention an occlusive pressure sufficient to support a 60-centimeter column of water as being the proper adjustment. Bartlett (Ref. 3) recommended 150 centimeters of water as the proper adjustment. In general, occlusive settings are accepted because they allow accurate flow calibration, have the feature of positive displacement, and their output does not depend on the resistance of the extracorporeal circuit (Ref. 1). The safety and effectiveness of roller pumps is proved daily by the results of thousands of cardiopulmonary bypass operations. The Panel believes that sufficient technical and clinical information is available to establish performance standards for roller pumps used in cardiopulmonary bypass surgery.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of car-

diac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Blood damage or damage to bypass circuit tubing resulting in embolic complications: Inadequate mechanical design of the pump can cause excessive compression of the tubing and blood, leading to the formation of blood clots and the splintering of particles from the tubing, thus forming potentially debilitating of fatal emboli. (c) Variability in stroke volume: Inadequate mechanical design of the pump head and torque developed in the pump head are characteristics of the device that can cause a variability in stroke volume, thereby reducing the physican's control over the flow rate in the bypass circuit.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the roller-type cardiopulmonary bypass blood pump be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

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Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4370 as follows:

§ 870.4370 Roller-type cardiopulmonary bypass blood pump.

(a) *Identification.* A roller-type cadiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6268 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1527]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Pump Speed Controls

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass pump speed controls into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass pump speed controls:

1. Identification: A cardiopulmonary pump speed control is a device that incorporates an electrical system or a mechanical system, or both, and is used to control the speed of blood pumps used in cardiopulmonary bypass surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass pump speed control by classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the cardiopulmonary bypass circuit through the blood pump and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's control of pump speed, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Inadequate or excessive flow: Inaccuracy or instability of the control system can lead to improper flow rates.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass pump speed control be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4380 as follows:

§ 870.4380 Cardiopulmonary bypass pump speed control.

(a) *Identification.* A cardiopulmonary bypass pump speed control is a device that incorporates and electrical system or a mechanical system, or both, and is used to control the speed of blood pumps used in cardiopulmonary bypass surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1978 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6269 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1528]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Pump Tubing

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass pump tubing into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposed become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass pump tubing:

1. Identification: Cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood to flow through the cardiopulmonary bypass circuit.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass pump tubing be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is part of the extracorporeal oxygenation circuit and is in direct contact with the blood. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Propensity to rupture: The material properties, stiffness, and electicity of the tubing are associated with the propensity to rupture. (b) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (c) Embolism: Pieces of the tubing which break or flake off may form potentially debilitating or fatal emboli.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass pump tubing be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4390 as follows:

§ 870.4390 Cardiopulmonary bypass pump tubing.

(a) *Identification.* Cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood to flow through the cardiopulmonary bypass circuit.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6270 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1529]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Blood Reservoirs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass blood reservoirs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass blood reservoirs:

1. Identification: A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve, supply of blood in the bypass circulation. (If a reservoir contains a defoamer or filter, it is classified into the same category as the defoamer or filter.)

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass blood reservoir be classified into class II because the device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device or inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass blood reservoir be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend part 870 in Subpart E by adding new § 870.4400 as follows:

§ 870.4400 Cardiopulmonary bypass blood reservoir.

(a) *Identification.* A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation. (If a reservoir contains a defoamer or filter, it is classified into the same category as the defoamer or filter.)

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6271 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1530]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass In-Line Blood Gas Sensors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass in-line blood gas sensors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass in-line blood gas sensors:

1. Identification: A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass in-line blood gas sensor be classified into Class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. This device is attached to the body through an extracorporeal blood circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to sense gas levels, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: Inadequate design with regard to blood gas information can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Embolism: Breakage of the sensor can form potentially debilitating or fatal particle emboli. (c) Blood damage: If the materials, surface finish, or cleanliness of this

device are inadequate, damage to the blood may result. (d) Toxic reaction: Breakage of the sensor can release toxic chemicals from the sensor into the bloodstream and cause a toxic reaction.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass in-line blood gas sensor be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4410 as follows:

§ 870.4410 Cardiopulmonary bypass in-line blood gas sensor.

(a) *Identification.* A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6272 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1531]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Cardiotomy Return Suckers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass cardiotomy return suckers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass cardiotomy return suckers:

1. Identification: A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass cardiotomy return sucker be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue and blood damage. If the materials, surface finish, or cleanliness of this device are inadequate, or if the probe tip is not designed properly, damage to the blood and tissue may result. (b) Damage to the heart: If the probe is too rough or too stiff damage to the heart may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass cardiotomy return sucker be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4420 as follows:

§ 870.4420 Cardiopulmonary bypass cardiotomy return sucker.

(a) *Identification.* A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6273 Filed 3-8-79; 8:45 a.m.]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1532]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Intracardiac Suction Controls

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass intracardiac suction controls into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER COMMENT CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass intracardiac suction controls:

1. Identification: A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass intracardiac suction control be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. The device develops a vacuum through an electrically powered source to permit the suction of blood from the chest cavity during open heart surgery. This device is attached to the body through the blood and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of the device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to control the amount of vacuum pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Blood and tissue damage: If the device produces excessive or unstable vacuum pressure, damage to the blood and tissue may result. (b) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass intracardiac suction control be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4430 as follows:

§ 870.4430 Cardiopulmonary bypass intracardiac suction control.

(a) *Identification.* A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in

brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6274 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1533]

MEDICAL DEVICES

Classification of Vascular Clamps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vascular clamps into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of vascular clamps:

1. Identification: A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the vascular clamp be classified into class II because the device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. The materials used in the device should be generally acceptable for surgical application, and the mechanical design of the device should minimize tissue damage. Pressure applied to a blood vessel should be great enough to stop the flow of blood but not so great as to cause tissue damage. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Tissue damage which may lead to thrombus formation: Improper mechanical design, inadequate tissue compatibility of the materials used in this device, or inadequate surface finish and cleanliness may lead to tissue damage which can cause potentially debilitating or fatal thrombus formations.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vascular clamp be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4450 as follows:

§ 870.4450 Vascular clamp.

(a) *Identification.* A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6275 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1534]

MEDICAL DEVICES

Classification of Surgical Vessel Dilators

AGENCY: Food and Drug Administration

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying surgical vessel dilators into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of surgical vessel dilators:

1. Identification: A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the surgical vessel dilator be classified into class II because the device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. Because the device is placed in direct contact with the bloodstream and the vessel walls it should be designed and constructed to minimize blood and tissue damage. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Damage to the vessel. If the materials, surface finish or cleanliness of the device are inadequate, damage to the vessel may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the surgical vessel dilator be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4475 as follows:

§ 870.4475 Surgical vessel dilator.

(a) *Identification.* A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6276 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1535]

MEDICAL DEVICES

Classification of Cardiovascular Surgical Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiovascular surgical instruments into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that these devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department Of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiovascular surgical instruments:

1. Identification: Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiovascular surgical instruments be classified into class II because the devices are neither life-supporting nor life-sustaining but are potentially hazardous to life and health even when properly used. Because these devices are used in cardiovascular surgery and are in direct contact with body tissues, the materials used in the devices should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics

of these devices. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the devices and on their personal knowledge of, and experience with, the devices.

5. Risks to health: Tissue damage: If the materials, surface finish, or cleanliness of these devices are inadequate, damage to body tissues may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that cardiovascular surgical instruments be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4500 as follows:

§ 870.4500 Cardiovascular surgical instruments.

(a) *Identification.* Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6278 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1536]

MEDICAL DEVICES

Classification of Intraluminal Artery Strippers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intraluminal artery strippers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intraluminal artery strippers:

1. Identification: An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arterosclerotic arteries).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the intraluminal artery stripper be classified into class II because this device is neither life-supporting nor life-sustaining but is potentially hazardous to life and health even when properly used. The materials used in the device and the mechanical design of the device should meet a generally accepted satisfactory level for surgical applications and should minimize the possibility of vessel perforation. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Predisposition to perforation of the vessel: Improper mechanical design and surface finish can lead to vessel perforation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the intraluminal artery stripper be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4875 as follows:

§ 870.4875 Intraluminal artery stripper.

(a) *Identification.* An intraluminal artery stripper is a device used to per-

form an endarterectomy (removal of plaque deposits from arterosclerotic arteries).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6278 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1537]

MEDICAL DEVICES

Classification of External Vein Strippers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external vein strippers into class II (performance standards. The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external vein strippers:

1. Identification: An external vein stripper is an extravascular device used to remove a section of a vein.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the external vein stripper be classified into class II because this device is neither life-supporting nor life-sustaining but is potentially hazardous to life and health even when properly used. Because this device is used in cardiovascular surgery and comes into direct contact with the body, materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Tissue damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the tissue may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the external vein stripper be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable such assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4885 as follows:

§ 870.4885 External vein stripper.

(a) *Identification.* An external vein stripper is an extravascular device used to remove a section of a vein.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food, and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6279 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR PART 870]

[Docket No. 78N-1538]

MEDICAL DEVICES

Classification of Patient Care Suction Apparatus

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying patient care suction apparatus into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class

II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovaseular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of patient care suction appratus:

1. Identification: A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the patient care suction apparatus be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. The device is connected to the chest cavity via a catheter, providing a direct electrical pathway to the chest. Suction is developed electrically in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the patient care suction apparatus be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 by adding Subpart F and new § 870.5050 as follows:

Subpart F—Cardiovascular Therapeutic Devices

§ 870.5050 Patient care suction apparatus.

(a) *Identification.* A patient care suction apparatus is a device which is used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

(b) *Classification.* Class II (performamce standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6280 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1539]

MEDICAL DEVICES

Classification of Embolectomy Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying embolectomy catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of embolectomy catheters:

1. Identification: An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated

from blood vessels from one site in the vascular tree to another.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the embolectomy catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. Because it is placed directly in contact with the bloodstream, the device should be designed and constructed to minimize hemodynamic disruption and any foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. In addition, the material used for the balloon should not be excessively permeable to gas and should resist bursting under pressure at an accepted standard limit. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the catheter that break or flake off may form emboli which can be debilitating or fatal. (c) Gas embolism: A rupture or leak in the balloon can allow potentially debilitating or fatal gas emboli to escape into the bloodstream. (d) Damage to blood vessels: Overinflation of the balloon can lead to excess pressure on the blood vessels and cause damage to them.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the embolectomy catheter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5150 as follows:

§ 870.5150 **Embolectomy catheter.**

(a) *Identification.* An embolectomy catheter is a ballon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which migrate from blood vessels from one site to another in the vascular tree.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6281 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1540]

MEDICAL DEVICES

Classification of Septostomy Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying septostomy catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of septostomy catheters:

1. Identification: A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of infants.

2. Recommended classifications: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the septostomy catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. Because the device is placed directly in contact with the blood stream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness which may affect the degree of compatibility. In addition, the balloon should resist bursting under pressure at an acceptable limit. The Panel believes that general controls alone would not provide sufficient control

over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatability of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the catheter that break or flake off may form emboli which can be debilitating or fatal.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the septostomy catheters be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance stand would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs., 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5175 as follows:

§ 870.5175 Septostomy catheter.

(a) *Identification.* A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of infants.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6282 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1541]

MEDICAL DEVICES

Classification of External Cardiac Compressors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external cardiac compressors into class III (premarket approval). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel that the device be classified into class III, and the recommendation of the General Hospital and Personal Use Device Classification Panel that manually operated external cardiac compressors be classified into class III and that pneumatically and electrically powered external cardiac compressors be classified into class II. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of external cardiac compressors:

1. Identification: An external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest.

2. Recommended classification: The Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel recommend that external cardiac compressors be classified into class III (premarket approval) and that premarket approval of this device be a medium priority. The General Hospital and Personal Use Device Classification Panel recommends that manually operated external cardiac compressors be classified into class III and that pneumatically and electrically powered external cardiac compressors be classified into class II.

3. Summary of reasons for recommendations: The Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel recommend that external cardiac compressors be classified into class III because this device is life supporting and is potentially hazardous to life or health even when properly used. This device is attached directly to the body and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's compression rate and applied force, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The surface area of the plunger and the use of the device on infants and children are subjects which should be considered in the design and labeling of the device. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels also believe that a performance standard will not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a standard to provide such assurance.

The General Hospital and Personal Use Device Classification Panel agrees with the Class III recommendation for manual external cardiac compressors, but believes that, for pneumatically and electrically powered external cardiac compressors, a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendations are based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panels found further support for their recommendations in the medical literature. This device has the advantage of efficiency and consistency (Refs. 1 through 4). An external cardiac compressor does offer several advantages to the trained operator. The automatic compressor frees the operator and allows the operator to perform other duties (Refs. 3 and 4). Little, et al. (Ref. 3) claim that external cardiac compressors operate well during patient transport and control sternal deflection more precisely than does manual cardiopulmonary resuscitation (CPR). However, safe and effective use of this device requires extensive operator training, and there is a hazard associated with the required setup time during which cardiac compression is halted (Ref. 4). Several other hazards are associated with the use of the device. The device can cause fractures of the ribs and sternum (Refs. 5, 6, and 8), and heart (Refs. 5 through 8); damage to the liver (Refs. 5, 6, 8, and 9), lungs (Refs. 5 and 8); and possible bone marrow emboli (Ref. 8). However, these injures can also result from manual CPR and are relatively minor compared to the serious nature of cardiopulmonary arrest. The literature offers conflicting evidence regarding the efficacy of the external cardiac compressor as compared to manual CPR (Refs. 5, 7, 9, and 10). However, the device is not designed to replace manual CPR. The literature seems to recommend it for certain situations such as long-term applications and patient transport. Although some preliminary standards for the external cardiac compressor have been researched, addressing such parameters as compression rate, force, systolic/diastolic time interval, and degree of sternal deflection (Refs. 1 and 11), the Panels believe those efforts are inadequate to provide reasonable assurance of the safety and effectiveness of the device.

5. Risks to health: (a) Tissue damage, bone breakage, or inadequate blood flow: Damage to the heart, other organs or tissues, or inadequate blood flow can result from poor mechanical design, improper surface area of the plunger, improper vertical excursion of the plunger, improper force applied by the plunger, or improper energy transmission by the device. (b) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias.

Proposed Classification

The Commissioner agrees with the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel, and is proposing that the external cardiac compressor be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (for mechanically pumping the heart during cardiopulmonary resuscitation) in supporting or sustaining human health. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "External Cardiac Compressors," *Health Devices*, 2(6):136-150, 1973.

2. Boaz, R. R., and J. C. Findeiss, "Heart-Lung Resuscitators" *in* "Emergency Management of the Critical Patient," Edited by J. C. Findeiss, Stratton, New York, pp. 267-268, 1975.

3. Little, K., J. M. Auchincloss, and C. S. Reaves, "A Mechanical Cardiopulmonary Lifesupport System," *Resuscitation*, 3:63-68, 1974.

4. Allen, J. R., "The Use of the Life Aid Cardiopulmonary Resuscitator—Preliminary Report," *British Journal of Clinical Practice*, 28(8):286-288, 1974.

5. Saphir, R., "External Cardiac Massage," *Medicine*, 47(1):73-87, 1968.

6. Nachlas, M. M. and M. P. Siedband, "Clinical Experiences with Mechanized Cardiac Massage," *American Journal of Cardiology*, 15(3):310-319, 1965.

7. Murtomaa, M. and K. Korttila, "Experience of Cardiopulmonary Resuscitation Outside Hospital by a Mobile Intensive Care Unit," *Resuscitation*, 3:211-214, 1974.

8. Tambascia, J. J., "Mechanical External Cardiopulmonary Resuscitation," *Journal of the Medical Society of New Jersey*, 62(11):507-509, 1965.

9. Nachlas, M. M., D. I. Miller, and M. P. Siedband, "Determination of Cardiorespiratory Variables in Experimental Cardiac Resuscitation Using a Mechanized Pump for External Cardiac Massage," *Annals of Surgery*, 158(2):295-307, 1963.

10. Pearson, J. W., R. N. Navarro, and J. S. Redding, "Evaluation of Mechanical Devices of Closed-Chest Cardiac Massage," *Anesthesia and Analgesia*, 45(5):590-598, 1966.

11. Jude, J. R., "Current Standards in Cardiopulmonary Resuscitation," *in* "Emergency Management of the Critical Patient," Edited by J. C. Findeiss, Stratton, New York, pp. 19-25, 1975.

12. Nachlas, M. M. and M. P. Siedband, "A Simple Portable Pneumatic Pump for External Cardiac Massage," *American Journal of Cardiology*, 10(1):107-109, 1962.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5200 as follows:

§ 870.5200 External cardiac compressor.

(a) *Identification.* An external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6283 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1542]

MEDICAL DEVICES

Classification of External Counter-Pulsating Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external counter-pulsating devices into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external counter-pulsating devices:

1. Identification: An external counter-pulsating device is a noninvasive device used to assist the heart by applying positive or negative pressure to one or more of the body's limbs in synchrony with the heart cycle.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the external counter-pulsating device be classified into class III because this electrically or pneumatically powered device is life-supporting and is potentially hazardous to life or health even when properly used. This device surrounds the limbs to which it is attached, is in direct contact with the skin, and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproduciblity, and any limitations on the device's cardiac synchronization and pressure application, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that there is not sufficient information to establish a performance standard to provide assurance of the safety and effectiveness of the device and, therefore, that premarket approval is necessary for this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Trauma to the limb: Improper mechanical design can cause trauma to the limb to which the device is applied. (c) Ineffective cardiac assistance: Improper timing or a failure to synchronize with the appropriate phase of the cardiac cycle can lead to ineffective cardiac assistance by the device.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the external counter pulsating device be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (assisting a weak heart in pumping blood) in supporting or sustaining human health. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5225 as follows:

§ 870.5225 External counter-pulsating device.

(a) *Identification.* An external counter-pulsating device is a noninvasive device used to assist the heart by applying positive or negative pressure to one or more of the body's limbs in synchrony with the heart cycle.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6285 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1543]

MEDICAL DEVICES

Classification of DC-Defibrillators (Including Paddles)

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying DC- defibrillators (including paddles) into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of DC-defibrillators (including paddles):

1. Identification: A DC-defibrillator (including paddles) is a device used to produce an electrical shock for defibrillating (restoring normal heart rhythm) the atria or ventricals of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the DC-defibrillator (including paddles) be classified into class III because the device is life sustaining and presents a potential unreasonable risk of illness or injury. If the device fails to perform adequately, unnecessary heart damage or death may result.

Based upon the information available to it, the Panel has reviewed and revised its recommendation many times over the past several years. On July 30, 1976, the Panel recommended that defibrillators using damped sinusoidal wave forms be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II. The debate about the classification of defibrillators continued and, after reviewing significant additional data, the Panel, on April 7, 1978, voted to classify all damped sinusoidal defibrillators and trapezoidal defibrillators with delivered energies of 400 joules or less into class II and to classify all other defibrillators into class III. At the April 7, 1978 Panel meeting three classification motions for defibrillators were entertained. The vote on each motion was split, and after this meeting one Panel member indicated that he wished to change his vote on a motion to place the device into class III based upon the discussion which took place on a later motion to divide the device into a class II and class III category.

A summary of the safety and efficacy data for defibrillators was prepared and provided to each Panel member in November 1978. At that time, because of what had occurred at the April 7, 1978 meeting, each Panel member was asked to review the summary, to indicate if he or she believed the summary to be accurate, and then to vote to either: (1) Classify all defibrillators into class II; (2) classify all defibrillators into class III; (3) classify defibrillators with a maximum delivered energy equal to or less than 360 joules into class II and classify all others into class III; or (4) classify defibrillators with a maximum delivered energy equal to or less than 400 joules into class II and classify all others into class III. The result of that vote was that three members voted to classify all defibrillators into class III, and two members voted to classify some defibrillators into class II and others into class III.

The Panel's final recommendation is based on this last vote. During the discussions about classifying defibrillators, significant contradictory data were presented to the Panel. It became apparent that dividing the classification of the device between class II and class III subgroups could be unnecessarily detrimental to the development of those devices placed into class III.

Because of the controversy over delivered energy, wave form, duration, current, and other defibrillation parameters, the Panel believes that premarket approval is necessary for this device. The Panel also believes that general controls alone would not provide sufficient control over the performance characteristics of the device, and that sufficient data do not exist to establish a performance standard to assure the safety and effectiveness of the device. Because of the controversy surrounding the classification of defibrillators, the Panel has requested FDA to schedule a Panel meeting at which interested parties may present data on the safety and efficacy of defibrillators before a final regulation classifying the device is published in the FEDERAL REGISTER.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with the inherent properties of the device and on the Panel members' personal knowledge of, and experience with, the device. In addition, the Panel sought information from the medical and scientific community, the industry, and the medical literature.

Representatives of industry, concerned private medical practitioners, and individual panel members presented their views to the Panel. The Panel discussed the classification of this device at the following Panel meetings: March 15, 1976; July 30, 1976; October 18, 1976; January 14, 1977; April 4, 1977; July 29, 1977; October 7, 1977; January 13, 1978; April 7, 1978; and June 30, 1978.

The summary minutes (Refs. 1 through 10) of these meetings contain the data and discussions on which the Panel made its recommendation. The characteristics of the electrical shock used to defibrillate the heart include energy, charge, duration, average current, peak current, current density, voltage, power, and waveform. In addition to these characteristics, paddle size and paddle position can affect defibrillation effectiveness.

Many factors other than device-related properties can alter the defibrillation threshold of a patient, including the use of drugs such as lidocaine, the presence of a myocardial infarction, hypoxic and acidotic conditions, and endogenously liberated substances such as adrenalin. Much of the dabate about classification of defibrillators focused upon the amount of energy required to defibrillate a patient, espe-

cially a patient weighing over 100 kilograms.

There are two theories regarding the energy required for defibrillation. The first theory is a dose concept for defibrillation energy—as bodyweight increases the amount of energy required for defibrillation increases. Data in support of the first theory were presented by Geddes (Refs. 1 and 4), Grayzel (Ref. 9), Gordon (Ref. 9), Levin (Ref. 9), Gallagher (Ref. 9), Babbs (Ref. 9), and the Health Industries Manufacturers Association (Ref. 6) represented by Gallagher and Larsen.

A paper by Tacker, et al. (Ref. 11), which retrospectively studied defibrillation in 111 patients, presented an energy threshold curve relating energy to bodyweight and was cited, among other articles (Refs. 12 through 15), as indicating the need for higher energy defibrillation.

The second theory is that a dose concept based upon bodyweight is not valid and that higher energy defibrillation places the patient at a greater risk of heart damage without increasing the probability of successful defibrillation. Lown (Ref. 8) presented his data on human cardioversion from ventricular tachycardia and atrial fibrillation indicating that weight had no bearing upon the energy required to accomplish cardioverson.

Pantridge (Ref. 8) reviewed a study he had performed, where 100-percent successful defibrillation occured at a stored energy of 400 joules. Crampton (Ref. 8) reported a prospective study in which he achieved 98-percent successful defibrillation in 46 episodes involving patents weighing 91 to 225 kilograms with an average energy dose of 1.8 joules/kilogram. The average dose was 3.1 joules/kilogram in Crampton's study of 253 episodes involving patients of all weights. In conjunction with the energy-dose issue, the Panel also discussed the amount of energy required to cause heart damage.

Geddes (Ref. 8) indicated that, in dogs, 300 joules/kilogram will permanently stop the heart and that damage occurs at 15 times the defibrillation therehold.

Kerber (Ref. 9) reviewed his own study which showed no change in the myocardial contractility in dogs with shocks of 40- to 460-joules- delivered energy. Kerber also studied the level of CPK isoenzyme in the blood of 15 patients and suggested that 2 of those patients may have had some myocardial damage due to a 400-joule-delivered energy shock.

Lown (Ref. 8) indicated that, in his studies on dogs, 30 to 75 joules were required to defibrillate, and 400 joules produced significant lesions on the heart. Pantridge (Ref. 8) indicated that, due to multiple shocks in 25-kilogram dogs, the damage from 10 shocks of 400 joules is 7 times the damage from 20 shocks of 200 joules and 30 times the damage of 40 shocks of 100 joules.

However, Grayzel (Ref. 9), in referring to a study by Ewy (Ref. 16), indicated that no discernible difference was found between the damage due to 3 shocks of 1,000 joules and that due to 10 shocks of 300 juoles when applied to 23-kilogram dogs.

Babbs (Ref. 9) presented therapeutic effect curves for defibrillation of healthy dogs that showed a 50-percent effective dose of 1.5 joules/kilogram. Babbs' data also show that 1 to 2 percent damage is expected from shocks with 90-percent effectiveness and that 10-percent damage is expected from shocks with 99-percent effectiveness. Dr. Babbs defined damage as any detectable degree of myocardial necrosis by either gross or pathological examination. Another subject of debate in the classification of defibrillators was the electrical wavefrom used to defibrillate. There are now two types of waveform used for defibillation: the damped sinusoidal and the truncated exponential (trapezoidal). Geddes (Ref. 1) noted that defibrillation is possible with many waveforms provided the current and duration parameters are chosed properly.

Schuder (Ref. 1) indicated that successful defibrillation cannot be expected from an untruncated exponential waveform and that a long, low-amplitude tail may actually cause the heart to refibrillate after the initial portion of the waveform has defibrillated the heart. Larsen (Ref. 3) gave a presentation demonstrating that the waveform can be controlled and described in engineering terms to small tolerances. In referring to work performed by Tacker (Ref. 17), Geddes (Ref. 4) stated that, for trapezoidal waveforms, as the tilt increases the current and energy required for defibrillation increases, such that when the tilt reaches 95 percent the energy required with a trapezoidal waveform is approximately equal to that required with a damped sinusoidal waveform.

Geddes and Tacker (Ref. 3) presented references showing the effectiveness of various specific marketed defibrillator waveforms. Other issues involving defibrillator design discussed in much less detail by the Panel were peak and average current, duration, paddle size and position, current density, and charge. As regards peak current, Gallagher (Ref. 6) indicated that 60 to 70 amperes is the peak current range of currently marketed damped sinusoidal waveform defibrillators. Schuder (Ref. 1) stated that there is a minimum current amplitude required for defibrillation, but that the percentage of arrhythmias that occur following successful defibrillation increases rapidly as the current amplitude increases above a certain level. Geddes (Ref. 6) believes that average current rather than peak current may provide a more accurate comparison of waveforms.

Gordon (Ref. 9) said that, based on his enzyme studies, a steep rise time and high peak current are more damaging than other waveform characteristics. With respect to duration, Geddes (Ref. 6) indicated that currently marketed defibrillators have a duration of 4 to 12 milliseconds. Schuder (Ref. 1) stated that duration of greater than 8 milliseconds can successfully defibillate but that more consideration must then be placed upon waveform and energy.

Tacker (Ref. 1) indicated that the relative importance of duration, voltages, and currents for different waveforms is largely unknown. Ewy et al. (Refs. 18 through 21) and Geddes et al. (Ref. 22) extensively studied paddle size and position, They found no difference in defibrillation success between transchest or chest-to-back paddle positions so long as the left chest paddle was placed over the apex of the heart. Geddes (Ref. 6) stated that paddle position data were collected from animal studies and that there are no data related to paddle position on humans. Specific data on current density and charge were not presented to the Panel, although these properties are intimately related to paddle size and waveform, among other properties.

The Panel recognized the work in progress to standardize defibrillators, including the efforts of American Heart Association (Refs. 23 through 25) and the Utah Biomedical Test Laboratories (Ref. 26).

5. Risks to Health: (a) Electrical shock to operator: Improper electrical design of the device can lead to a serious electrical shock to the operator. (b) Inability to defibrillate or persistence of the arrhythmia: Inability to defibrillate or persistence of the arrhythmia may occur because of excessive energy, excessive current, insufficient energy, insufficient current, a difference between the indicated level of energy and the delivered level of energy, as delivered into a 50-ohm load, or excessive leakage current. (c) Inability to defibrillate: Inability to defibrillate may occur when certain drugs that can raise the defibrillation threshold are used. (d) Inability to defibrillate due to paddle design: Inability to defibrillate may result from inappropriate paddle size or inappropriate paddle location on the subject.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the DC-defibrillator be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (e.g., restoring a fibrillating heart to normal rhythm and function) in supporting or sustaining human life. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, because of the contradictory data presented and available, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance. At the Panel's request, the Commissioner is also announcing his intention to schedule a Panel meeting prior to the final classification of difibrillators at which interested parties are invited to present relevant scientific data regarding the safety and effectiveness of DC-defibrillators.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Summary Minutes of the Panel on Review of Cardiovascular Devises Ad Hoc Subcommittee on Defibrillators Meeting, March 15, 1976.

2. Summary Minutes of the Panel on Review of Cardiovascular Devises, Joint Meeting of the Implants and Monitors Subcommittees, July 30, 1976.

3. Summary Minutes of the Panel on Review of Cardiovascular Devises Meeting, October 18, 1976.

4. Summary Minutes of the Cardiovascular Devises Classification Panel Meeting, January 14, 1977.

5. Summary Minutes of the Cardiovascular Devises Classification Panel Meeting, April 4, 1977.

6. Summary Minutes of the Cardiovascular Devises Classification Panel Meeting, July 29, 1977.

7. Summary Minutes of the Cardiovascular Device Classification Panel Meeting, October 7, 1977.

8. Summary Minutes of the Cardiovascular Device Classification Panel Meeting, January 13, 1978.

9. Summary Minutes of the Cardiovascular Device Classification Panel Meeting, April 7, 1978.

10. Summary Minutes of the Circulatory System Devices Panel Meeting, June, 30, 1978.

11. Tacker, W. A., Jr., F. M. Galioto, Jr., E. Giuliani, L. A. Geddes, D. C. McNamara, "Energy Dosage for Human trans-Chest Electrical Ventricular Defibrillation," *New England Journal of Medicine*, 290:214-215, 1974.

12. Geddes, L. A., W. A. Tacker, Jr., J. P. Rosborough, et al., "Electrical Dose for Ventricular Defibrillation of Large and Small Animals Using Precordial Electrodes," *Journal of Clinical Investigations*, 53:310-319, 1974.

13. Tacker, W. A., Jr., L. A. Geddes, J. P. Rosborough, "Trans-Chest Ventricular Defibrillation of Heavy Subjects Using Trapezoidal Current Waveforms," *Journal of Electrocardiology*, 8(3):237-240, 1975.

14. Gold, J. H., J. C. Schuder, H. Stoeckle, T. A. Granberg, S. Z. Hamdani, J. M. Rychlewski, "Transthoracic Ventricular Defibrillation in the 100 kg Calf with Unidirectional Rectangular Pulses," *Circulation*, 56(5):745-750, 1977.

15. Anderson, G. J., J. Suelzer, "The Efficacy of Trapezoidal Wave Forms for Ventricular Defibrillation," *Chest*, 70(2):298-300, 1976.

16. Ewy, G. A., D. Taren, P. W. Kohnen, "Comparison of Myocardial Damage from DC Defibrillator Discharge Delivered at Frequent Small Doses vs. Infrequent Large Doses," Proceedings of the 13th Annual AAMI Meeting, Washington, D.C., p. 88, 1978.

17. Tacker, W. A., Jr., L. A. Geddes, J. D. Bourland, M. Hinds, "The Effect of Tilt on the Strength-Duration Curve for Trans-Chest Ventricular Defibrillation," Proceedings of the 12th Annual AAMI Meeting, San Francisco, p. 403, 1977.

18. Ewy, G. A., "Effectiveness of Direct Current Defibrillation: Role of Paddle Electrode Size: II," *American Heart Journal*, 93(5):674-675, 1977.

19. Thomas, E. D., G. A. Ewy, C. F. Dahl, M. D. Ewy, "Effectiveness of Direct Current Defibrillation: Role of Paddle Electrode Size," *American Heart Journal*, 93(4):463-467, 1977.

20. Dahl, C. F., G. A. Ewy, E. D. Warner, E. D. Thomas, "Myocardial Necrosis from Direct Current Counter shock: Effect of Paddle Size and Time Interval Between Discharges," *Circulation*, 50:956-961, 1974.

21. Connell, P. N., G. A. Ewy, C. F. Dahl, M. D. Ewy, "Transthoracic Impedance to Defibrillator Discharge: Effect of Electrode Size and Electrode-Chest Wall Interference," *Journal of Electrocardiology*, 6(4):313-317, 1973.

22. Geddes, L. A., S. S. Grubbs, P. G. Wilcox, W. A. Tacker, Jr., "The Thoracic Windows for Electrical Ventricular Defibrillation Current," *American Heart Journal*, 94(1):67-72, 1977.

23. Report of the Intersociety Commission on Heart Disease Resources, "Electronic Equipment in Critical Care Areas Part I: Status of Devices Currently in Use," *Circulation*, 43:5-26, 1971.

24. Report of the Intersociety Commission on Heart Disease Resources, "Electronic Equipment in Critical Care Areas Part III: Selection and Maintenance Program," *Circulation*, 44:A247-A261, 1971.

25. Report of the American Heart Association Target Activity Group: Cardiopulmonary Resuscitation in the Young, "Guidelines for Defibrillation in Infants and Children," *Circulation*, 56(3): 502A-503A, 1977.

26. Standard for Cardiac Defibrillator Devices, Sixth Draft, Utah Biomedical Test Laboratories, FDA Contract—MDS-021-0001, Feb. 15, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5300 as follows:

§ 870.5300 DC-defibrillators (including paddles).

(a) *Identification.* A DC-defibrillator (including paddles) is a device used to produce an electrical shock for defibrillating (restorating normal heart rhythm) the atria or ventricals of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Assoicated Commissioner for Regulatory Affairs.

[FR Doc. 79-6285 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1544]

MEDICAL DEVICES

Classification of Defibrillator Testers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying defibrillator testers into

class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fisher Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provided background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of defibrillator testers:

1. Identification: A defibrillator tester is a device that is connected to the output of the defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the defibrillator tester be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Failure of the device to accurately measure defibrillator output can lead to excessive or insufficient energy delivered to a patient during defibrillation. Performance characteristics, including accuracy and reproducibility, and any limitations on the device's ability to measure defibrillator output should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: Inadequate design with regard to indication of defibrillator output can lead to generation of inaccurate defibrillator output data. If inaccurate defibrillator output data are used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

(b) Electrical shock to operator: Improper electrical isolation can lead to electrical shock to the operator.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the defibrillator tester be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5325 as follows:

§ 870.5325 **Defibrillator tester.**

(a) *Identification.* A defibrillator tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6286 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1545]

MEDICAL DEVICES

Classification of External Transcutaneous Cardiac Pacemakers (Noninvasive)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for Public comment a proposed regulation classifying external transcutaneous cardiac pacemakers (noninvasive) into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Wel-

fare, 8757 Georgia Ave., Silver Spring, Md 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

. A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external transcutaneous cardiac pacemakers (noninvasive):

1. Identification: An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the external transcutaneous cardiac pacemaker (noninvasive) be classified into class III because this device is life-supporting and presents a potential unreasonable risk of illness, injury or death. This device is most frequently used in emergency care situations where the introduction of a cardiac lead is impractical or impossible. The Panel is concerned that there is not enough information on energy levels and electrode configurations needed for reliable pacing. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. Although some electrical safety aspects can be controlled by standards, the Panel believes there is insufficient scientific and medical data for this life-supporting product to establish a standard that can assure safety and efficacy. Therefore, the Panel believes that premarket approval is necessary.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Myocardial or tissue damage: Excessive energy or poor electrode design and placement can cause tissue damage or myocardial damage. (b) Failure to pace: The pacemaker will not pace the heart if inadequate energy levels are used, or if a poor electrode design or configuration is employed.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the external transcutaneous cardiac pacemaker (noninvasive) be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human health. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5550 as follows:

§ 870.5550 External transcutaneous cardiac pacemaker (noninvasive).

(a) *Identification.* An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6287 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1546]

MEDICAL DEVICES

Classification of Compressible Limb Sleeves

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying compressible limb sleeves into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of compressible limb sleeves.

1. Identification: A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by

inflating periodically a sleeve around the limb.

2. Recommended classification: Class II (performance standards): The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reason for recommendation: The Panel recommends that the compressible limb sleeve be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when primarily used. The device fits around the extremities of the body and applies periodic pressure to the limb by pneumatic action. Malfunction of the device can result in unsafe excess pressure. The Panel believes that the pressure limits should be controlled by performance standards. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue trauma: Overinflation of the sleeve, associated with excess local pressure, can lead to tissue trauma. (b) Tissue damage: Tissue compatibility to the sleeve material is related to allergic and other similar or related skin reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the compressible limb sleeve be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5800 as follows:

§ 870.5800 Compressible limb sleeve.

(a) *Identification.* A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be see in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6288 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1547]

MEDICAL DEVICES

Classification of Thermal Regulating Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying thermal regulating systems into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of thermal regulating systems:

1. Identification: A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperture controller for the device. The system is used to regulate a patient's temperature.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the thermal regulating system be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. The device is used to warm or cool a patient. Malfunction of the device is potentially hazardous to life and health. Performance characteristics, including accuracy and reproducibility, and any limitations on the device's thermal properties should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the

device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Thermal tissue damage: Inaccuracy of temperature control can lead to burns or tissue damage related to hypotermia. (c) Mechanical tissue damage: Excessive pressure can cause the device to harden to the point of causing pressure necrosis, especially during hypothermia. (d) Chemical tissue damage: The integrity of the fluid chambers of the device can be violated by excessive pressure-causing fluids such as ethylene glycol contacting the skin and causing chemical tissue damage.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the thermal regulating system be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls, by themselves, are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5900 as follows:

§ 870.5900 Thermal regulating system.

(a) *Identification.* A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate patient temperature.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this douc-ment. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6289 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1548]

MEDICAL DEVICES

Classification of Automatic Rotating Tourniquets

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automatic rotating tourniquets into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of automatic rotating tourniquets:

1. Identification: An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the automatic rotating tourniquet be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. The device is placed around the patient's limbs. It can be either mechanically or electrically operated. Excessive or prolonged pressure applied by the device can lead to tissue damage by reducing blood flow to distal areas of the body. This device is attached directly to the surface of the body and is used in a clinical environment where excessive leakage current can be a serious hazard. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's mechanical design should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeing. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Tissue damage: If the mechanical design of the device causes excessive or prolonged pressure on a limb, tissue damage due to the pressure or lack of blood flow can result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommnedation and is proposing that the automatic rotating tourniquet be classified into class II (performance standards). The Commissioner believes that a performance

standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5925 as follows:

§ 870.5925 Automatic rotating tourniquet.

(a) *Identification.* An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6290 Filed 3-8-79; 8:45 am]

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